What is the Most Effective Use of the 1-Year Planning Phase?

Lessons Learned from EMBED

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NIH Collaboratory Panel Discussion

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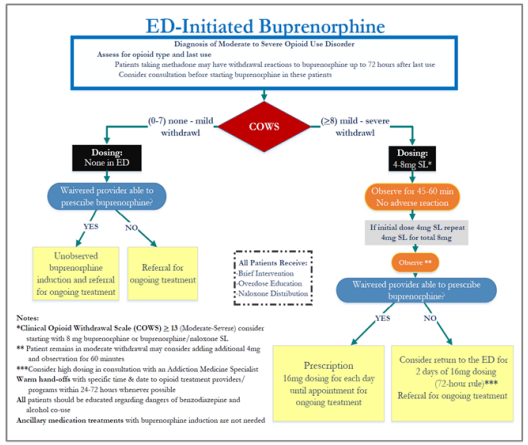
NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

EMBED: UG3-UH3 Project – An Introduction

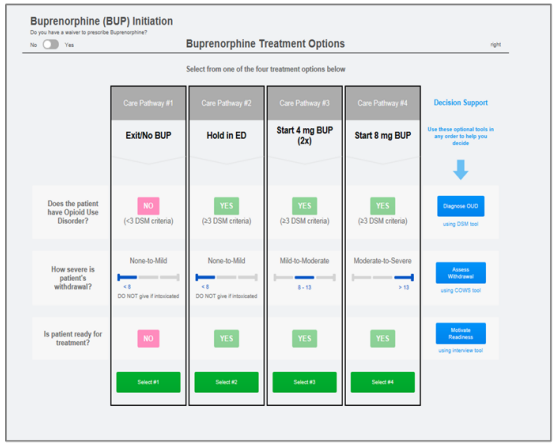
EMBED: *A Pragmatic Trial of User Centered Clinical Decision Support for **EM**ergency Department Initiated **B**uprenorphin**E** for Opioid Use **D**isorder*

- 5-year project
  - Y1 = UG3 – Planning phase ;
  - Y2-5 = UH3 Trial Implementation & Dissemination

- **EMBED Trial**
  - 18-month, pragmatic, parallel, group randomized trial
  - 21 ED sites, 5 healthcare systems,
    1. Yale New Haven Health System
    2. University of North Carolina-Chapel Hill
    3. University of Alabama-Birmingham
    4. University of Massachusetts-Baystate
    5. University of Colorado, Aurora
  - **Intervention:** user centered CDS to support diagnosis & withdrawal assessment & automate orders, notes, Rx, AVS, referral
  - Randomized, 1:1 ratio, Intervention vs usual care arm
  - **Primary outcome**: initiation of BUP in ED at patient level



From a multi-step manual process (**20-25min**), using a paper-based protocol as reference …



…to a **simple, automated** application (**5min**) that is –
- Entirely **EHR integrated**
- **User-centered** CDS, that automates –
  1. Diagnosis of OUD
  2. Withdrawal Assessment (COWS)
  3. Patient readiness assessment & motivation
  4. Dose calculation
  5. Automating EHR workflow including –
     a. Order entry
     b. Prescribing
     c. Clinical and after visit documentation

ClinicalTrials.gov Identifier: NCT03658642

National Institute on Drug Abuse
Advancing Addiction Science

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EMBED UG3 Planning Phase - Y1 Milestones

I. **Design and development of CDS prototype**

- Workflow analysis
- Initial prototype design
- Iterative design feedback
- Final prototype testing: Usability & field testing

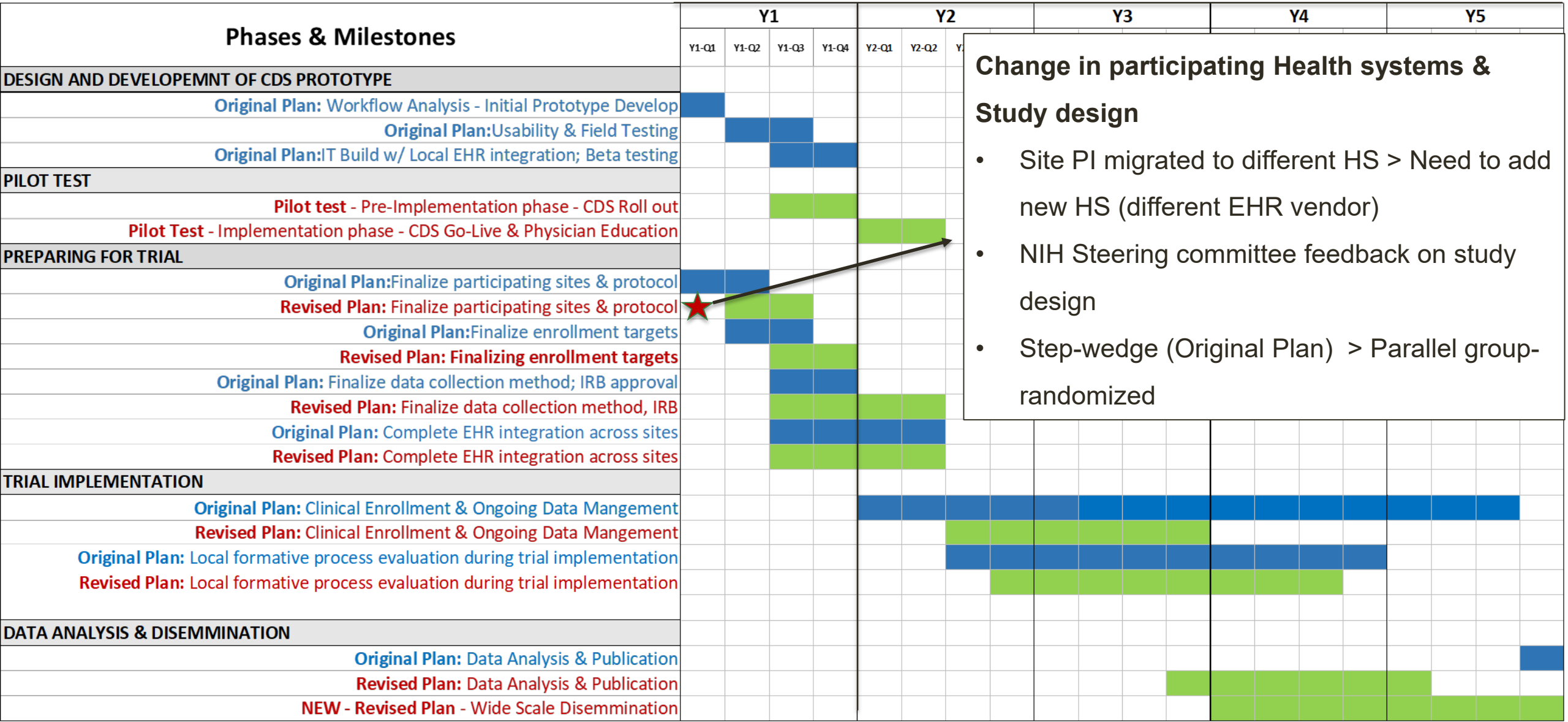
II. **IT Build with local EHR Integration – Beta Testing**

- Derivation and Validation of an EHR-Based Computable Phenotype
- Scalable, Automated Warm Handoff from the ED to Community Providers
- Integrated Web Application and Automation of EHR Workflow
- 1 site - Pilot Study

IV. **Trial Planning Phase**

- Finalize trial protocol
- Finalize participating sites, Finalize enrollment targets, Randomization
- Finalize data collection method
- Finalize Master Data Dictionary, Codes
- Complete Data Validation
- Complete EHR integration across all site
- IRB Approval
- Check Site Readiness **(Checklist)**

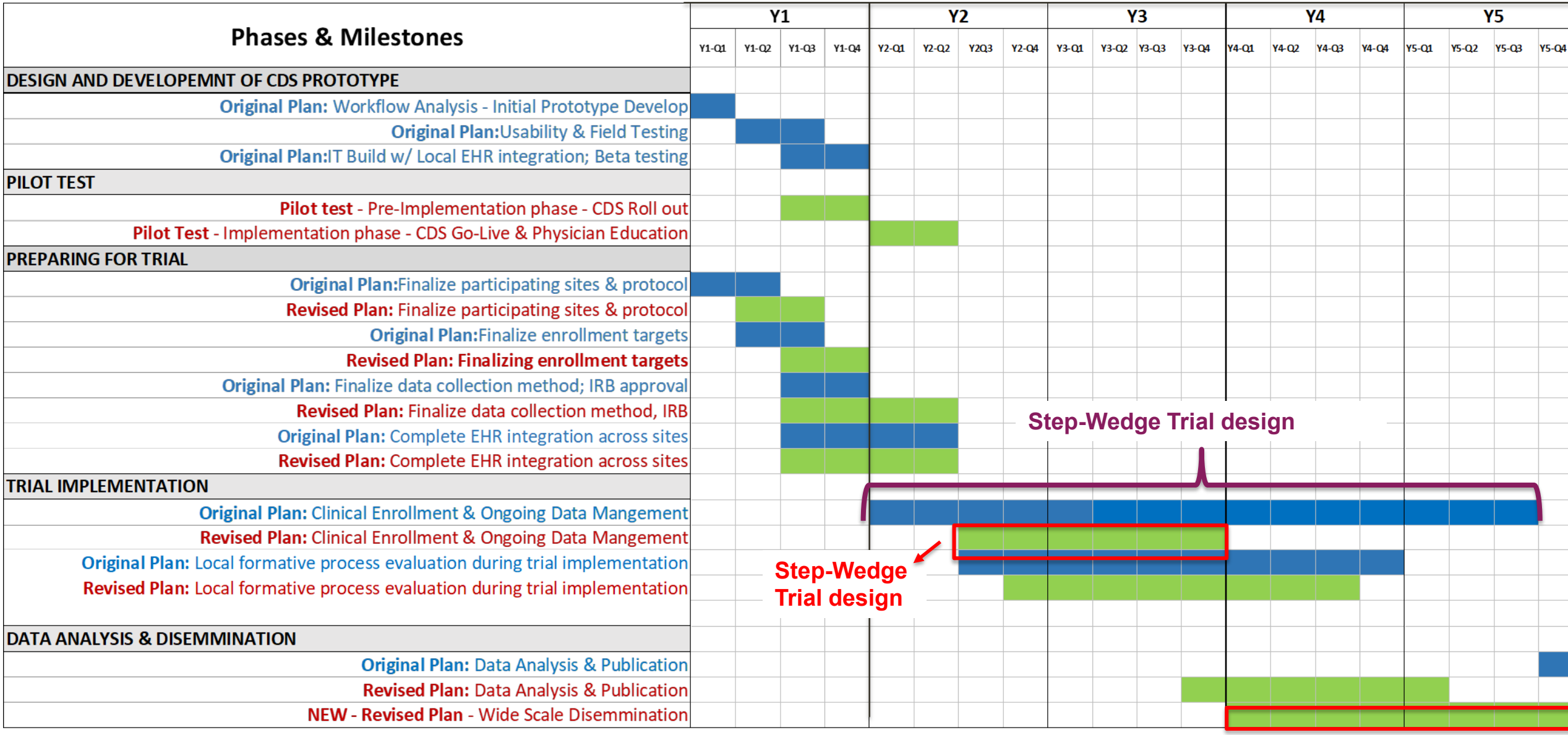
Y1 - **Change in Study Design**, timelines, participating health systems



Change in participating Health systems & Study design

- Site PI migrated to different HS > Need to add new HS (different EHR vendor)
- NIH Steering committee feedback on study design
- Step-wedge (Original Plan) > Parallel group-randomized

Revised Timelines under new Study Design



EMBED EHR Integration: Issues, Barriers and Solutions

Issue	Barrier	Solution
Usability	Vendor-provided CDS tools have limited capabilities for interface customization to develop intuitive, efficient user interfaces and workflow	Created an integrated web application that embedded into EHR clinical workflow for the end-user
	Needed to support health systems in the trial network using different EHR vendors (Epic and Cerner)	
Two-way communication between EHR and web application	FHIR standard does not yet cover enough resources and two-way ("read /write") communication for many FHIR resources is still not widely available. SMART on FHIR tools have limited capability to directly interact with an EHR API. Real-time interaction (order entry and documentation) cannot be pushed back to EHR from a web app.	Short-term: Epic AGL and flowsheet solution in main health system. Secondary health system has to rebuild web-app features in EMR vendor tool resulting in multiple separate instantiations of protocol.
		Long-term: await maturation of FHIR, SMART on FHIR or similar standards for interoperability
Institutional IT support	Some secondary health systems reluctant to invest in hosting and supporting a custom web application on-premise	Designed a lightweight, single-page web application running on open source technologies, to maximize flexibility in hosting and minimize infrastructure requirements
		Long-term: consider centralized, secure hosting of the web application in software as a service (SaaS) model
	Security and privacy concerns from secondary health systems	Utilized secure methods that pass no protected health information outside the EHR to the web application. Achieved independent, third-party security audit and certification for the provided web application.
Stakeholder buy-in and alignment	Informatics leadership in secondary systems reluctant to change established, local interfaces and workflows with which users are already familiar	Secondary health systems made local, pragmatic decisions on how the intervention was built in their system provided it allowed for decision support for diagnosing OUD, assessing withdrawal, and automating documentation, orders, prescriptions, referral, and discharge instructions
	Informatics leadership reluctant to take responsibility for updating of local instance of EMBED CDS as protocol or other variables change over time ("technology debt")	No solution until progress is made in standards-based interoperability
Referral to community providers for continued medications for opioid use disorder (MOUD)	Limited availability of community providers of MOUD. Even if available, often not on the same vendor's EHR product	Used platform-agnostic secure messaging
		Engaged local care coordination teams
		Piggy-backed onto other local MOUD initiatives
Governance	Prioritization of intervention required review by local committees in each health system.	Early engagement with informatics leadership to accelerate EHR prioritization requests and navigation of local governance norms to maximize the time available for local implementation of intervention
	Sometimes multiple committees in the same system.	
Human resources	Limited workforce available to make changes in local EHR build	Leveraged local physician builders, where available

Data Collection Challenges - Things to consider during Planning Phase

1. **Repeated, careful and rigorous checks to ensure fidelity of data collection process to local workflow and trial data collection plan.**
    - Ensure accurate mapping of EHR field and local workflow at each site
    - If working across multiple EHR vendors, ensure additional time to accommodate EHR vendor differences in variable mapping
    - Rigorous careful validation and review of sample data pull will reduce unwanted delays and errors during trial
    - For pragmatic trials with complicated data collection plan, plan for **monthly data pull during trial (vs 1 single data pull at the end) -** Helps to avoid identification of issues at last minute when it might be too late to intervene
    - Despite following all these rigorous steps, we still had challenges

2. **Inconsistent coding practice for race/ethnicity** – coding practice related to patient race/ethnicity can vary not only from system to system but within system, requiring multiple iterations to reconcile.

3. **Variables with Non-EHR data source (eg:** clinician age, gender, X-waiver status and date) –rely on local departmental records, may face bureaucratic red tapes – process for collecting those data requires planning ahead and close coordination with individual teams

4. **Maximize diversity and equity –** Plan target population with a goal to Maximize diversity and equity -

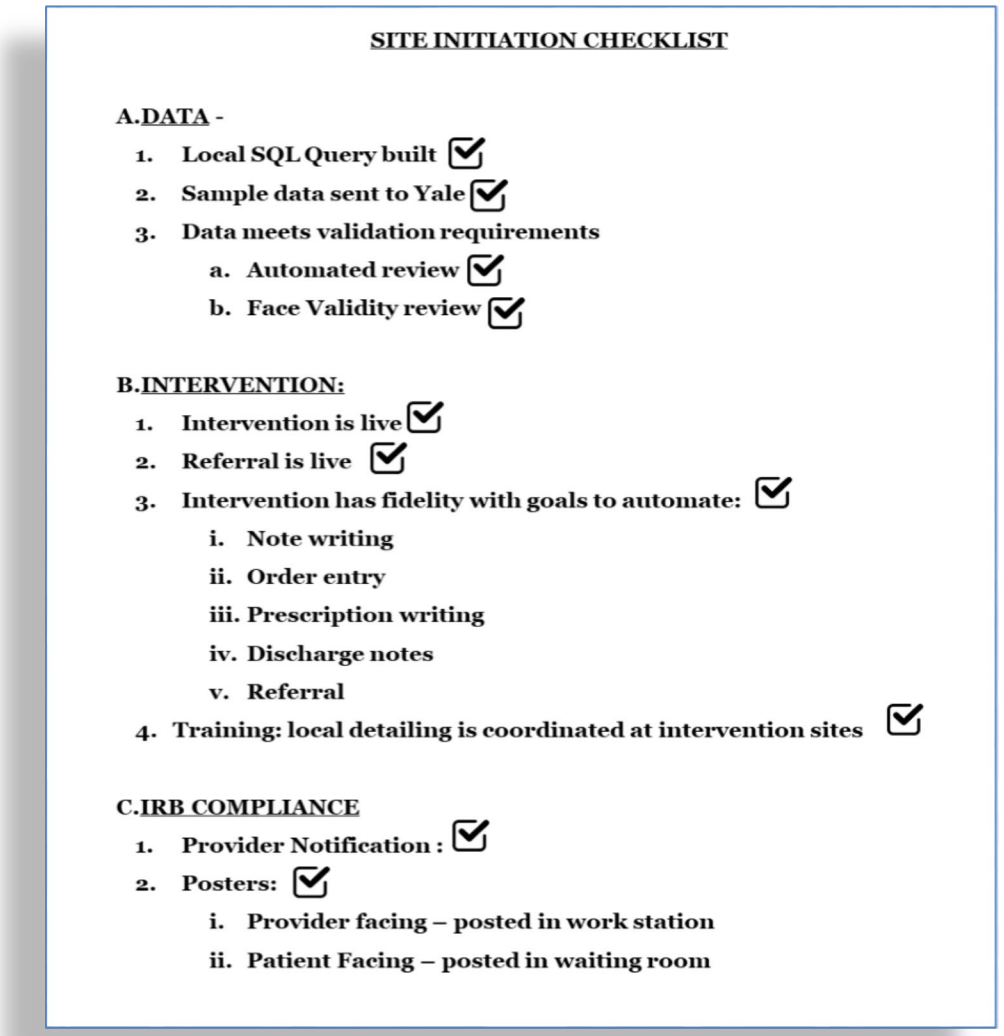
Planning Phase: Site Readiness Checklist

Prepare checklist to ensure site readiness in –

A. **Data Collection**
   1. Ensure infrastructure in place for data collection – local SQL Query is built
   2. Sample data collected and validated by investigative team

B. **Intervention**
   1. Intervention is LIVE or ready to go live
   2. Intervention fidelity is ensured
   3. Training/education of local clinician staff

C. **IRB Compliance:** All milestones reached from IRB compliance standpoint



SITE INITIATION CHECKLIST

A. DATA -
1. Local SQL Query built ☑
2. Sample data sent to Yale ☑
3. Data meets validation requirements
   a. Automated review ☑
   b. Face Validity review ☑

B. INTERVENTION:
1. Intervention is live ☑
2. Referral is live ☑
3. Intervention has fidelity with goals to automate: ☑
   i. Note writing
   ii. Order entry
   iii. Prescription writing
   iv. Discharge notes
   v. Referral
4. Training: local detailing is coordinated at intervention sites ☑

C. IRB COMPLIANCE
1. Provider Notification : ☑
2. Posters: ☑
   i. Provider facing – posted in work station
   ii. Patient Facing – posted in waiting room

EMBED Related Publications (Y1)

1. **Design & Development of CDS Prototype:** Ray J, Ahmed O, Solad Y, Maleska M, Martel S, Jeffery M, Platts-Mills T, Hess E, D'Onofrio G, Melnick E. Computerized Clinical Decision Support System for Emergency Department–Initiated Buprenorphine for Opioid Use Disorder: User-Centered Design. JMIR Hum Factors 2019;6(1):e13121 URL: https://humanfactors.jmir.org/2019/1/e13121. DOI: 10.2196/13121

2. **Derivation and Validation of an EHR-Based Computable Phenotype:** Chartash D, Paek H, Dziura J, Ross B, Nogee D, Boccio E, Hines C, Schott A, Jeffery M, Patel M, Platts-Mills T, Ahmed O, Brandt C, Couturier K, Melnick E. Identifying Opioid Use Disorder in the Emergency Department: Multi-System Electronic Health Record–Based Computable Phenotype Derivation and Validation Study. JMIR Med Inform 2019;7(4):e15794. URL: https://medinform.jmir.org/2019/4/e15794. DOI: 10.2196/15794

3. **Infrastructure evaluation for a Scalable, Automated Warm Handoff Referral from the ED to Community Providers:** Ahmed OM, Mao JA, Holt SR, Hawk K, D'Onofrio G, Martel S, Melnick ER. A scalable, automated warm handoff from the emergency department to community sites offering continued medication for opioid use disorder: Lessons learned from the EMBED trial stakeholders. J Subst Abuse Treat. 2019 Jul;102:47-52. doi: 10.1016/j.jsat.2019.05.006. Epub 2019 May 7. PMID: 31202288; PMCID: PMC6578846.

4. **Challenges to Integrated Web Application and Automation of EHR Workflow.** Edward R Melnick, Wesley C Holland, Osama M Ahmed, Anthony K Ma, Sean S Michael, Howard S Goldberg, Christian Lagier, Gail D'Onofrio, Tomek Stachowiak, Cynthia Brandt, Yauheni Solad, An integrated web application for decision support and automation of EHR workflow: a case study of current challenges to standards-based messaging and scalability from the EMBED trial, JAMIA Open, Volume 2, Issue 4, December 2019, Pages 434–439, https://doi.org/10.1093/jamiaopen/ooz053

5. **Pilot Study.** Holland WC, Nath B, Li F, Maciejewski K, Paek H, Dziura J, Rajeevan H, Lu CC, Katsovich L, D'Onofrio G, Melnick ER. Interrupted Time Series of User-centered Clinical Decision Support Implementation for Emergency Department-initiated Buprenorphine for Opioid Use Disorder. Acad Emerg Med. 2020 Aug;27(8):753-763. doi: 10.1111/acem.14002. Epub 2020 May 19. PMID: 32352206; PMCID: PMC7496559.

6. **EMBED Trial Protocol.** Melnick ER, Jeffery MM, Dziura JD, Mao JA, Hess EP, Platts-Mills TF, Solad Y, Paek H, Martel S, Patel MD, Bankowski L, Lu C, Brandt C, D'Onofrio G. User-centred clinical decision support to implement emergency department-initiated buprenorphine for opioid use disorder: protocol for the pragmatic group randomised EMBED trial. BMJ Open. 2019 May 30;9(5):e028488. doi: 10.1136/bmjopen-2018-028488. PMID: 31152039; PMCID: PMC6550013.

7. **EMBED Progress Report.** Melnick ER, Nath B, Ahmed OM, Brandt C, Chartash D, Dziura JD, Hess EP, Holland WC, Hoppe JA, Jeffery MM, Katsovich L, Li F, Lu CC, Maciejewski K, Maleska M, Mao JA, Martel S, Michael S, Paek H, Patel MD, Platts-Mills TF, Rajeevan H, Ray JM, Skains RM, Soares WE 3rd, Deutsch A, Solad Y, D'Onofrio G. Progress Report on EMBED: A Pragmatic Trial of User-Centered Clinical Decision Support to Implement EMergency Department-Initiated BuprenorphinE for Opioid Use Disorder. J Psychiatr Brain Sci. 2020;5:e200003. doi: 10.20900/jpbs.20200003. Epub 2020 Feb 21. PMID: 32309637; PMCID: PMC7164817.