

A Streamlined Process for Electronic Case Report Form Development

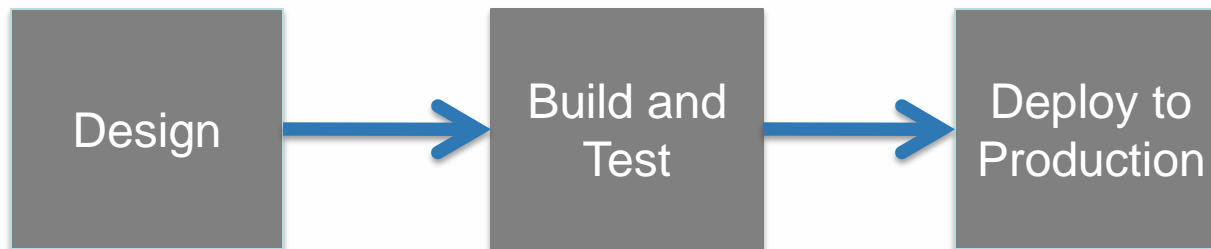
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Outline

- Motivation for Improving electronic Case Report Form (eCRF) Process
- Preparatory Activities
- Three Phases for eCRF creation



- Examples: small pilot grant, pharma sponsored Investigator Initiated Trial (IIT), NIH grant

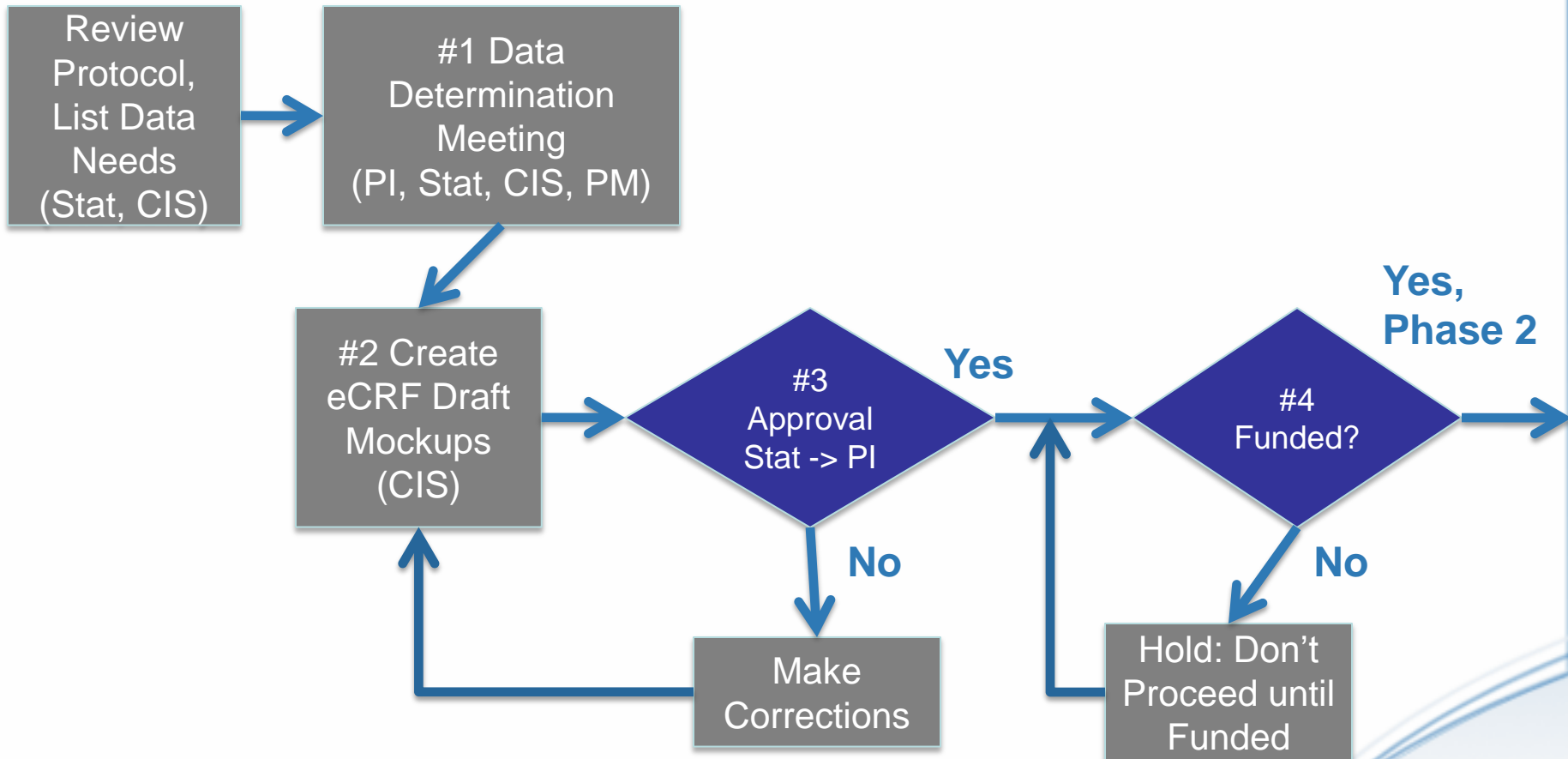
Motivation

- Multidisciplinary input needed to create eCRFs
 - Principal Investigator (PI), Data Coordinators, Nurses
 - Biostatistician (Stat), Senior Research Analyst (SRA), Project Managers (PM), Clinical Information Specialist (CIS), Quality Assurance (QA), Computer Application Administrator (CAA)
- We had an inconsistent process
 - Where are we in the process? Who approves next?
 - Pressures and requests to create eCRFs without analysis and prior to funding
 - Overpromising: using the vendor's framework versus writing "custom code" (either javascript or server side software modules)

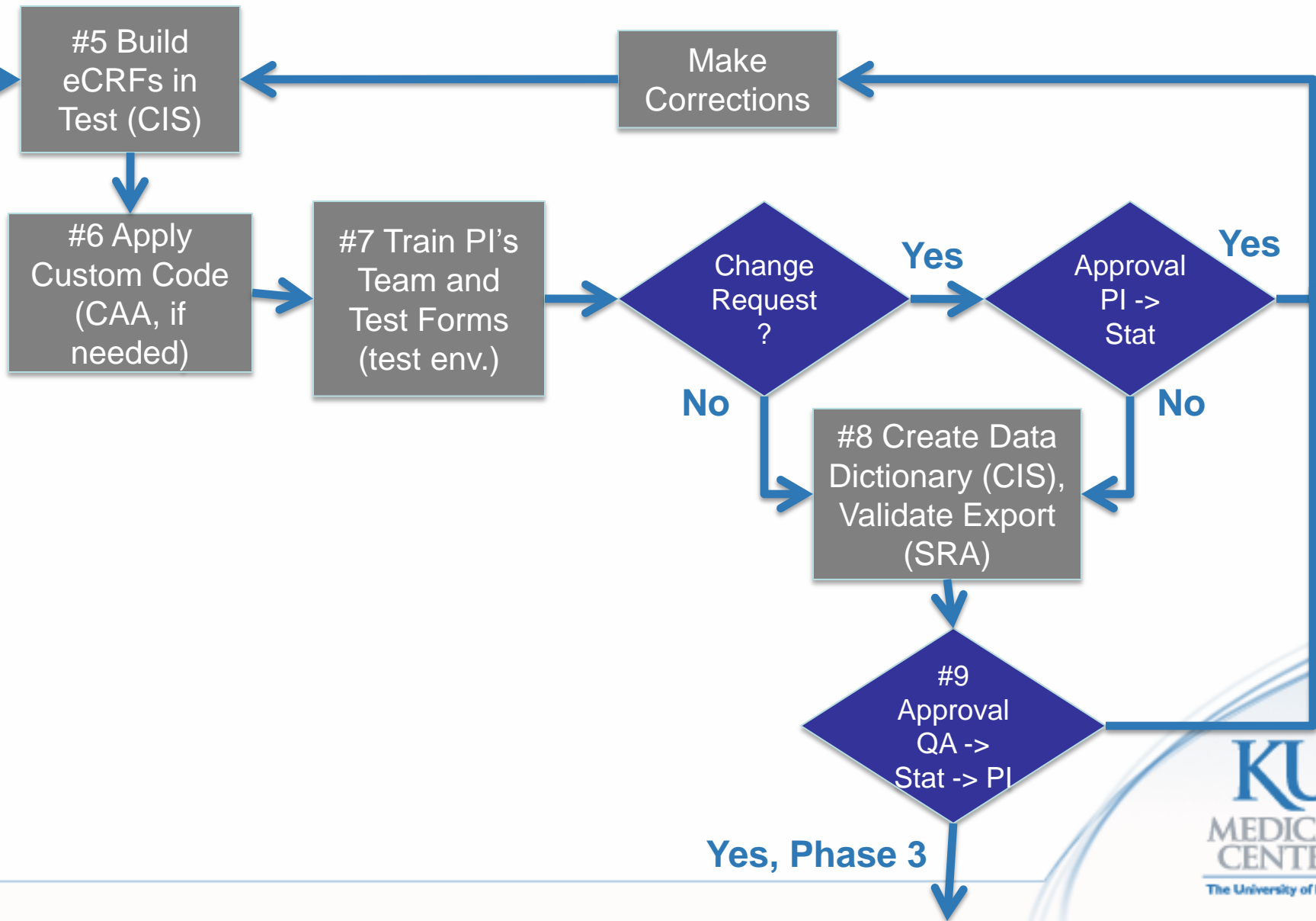
Activities before the eCRF Process

- Initial Meeting: Principal Investigator, Pre-award Project Manager, Biostatistician (sometimes Informatics)
- Budget Development
- Protocol Development
- Scientific and Human Subjects Review:
 - Follows acceptance of protocol/budget by the sponsor
 - For cancer trials, Protocol Review and Monitoring Committee (PRMC) prior to Institutional Review Board

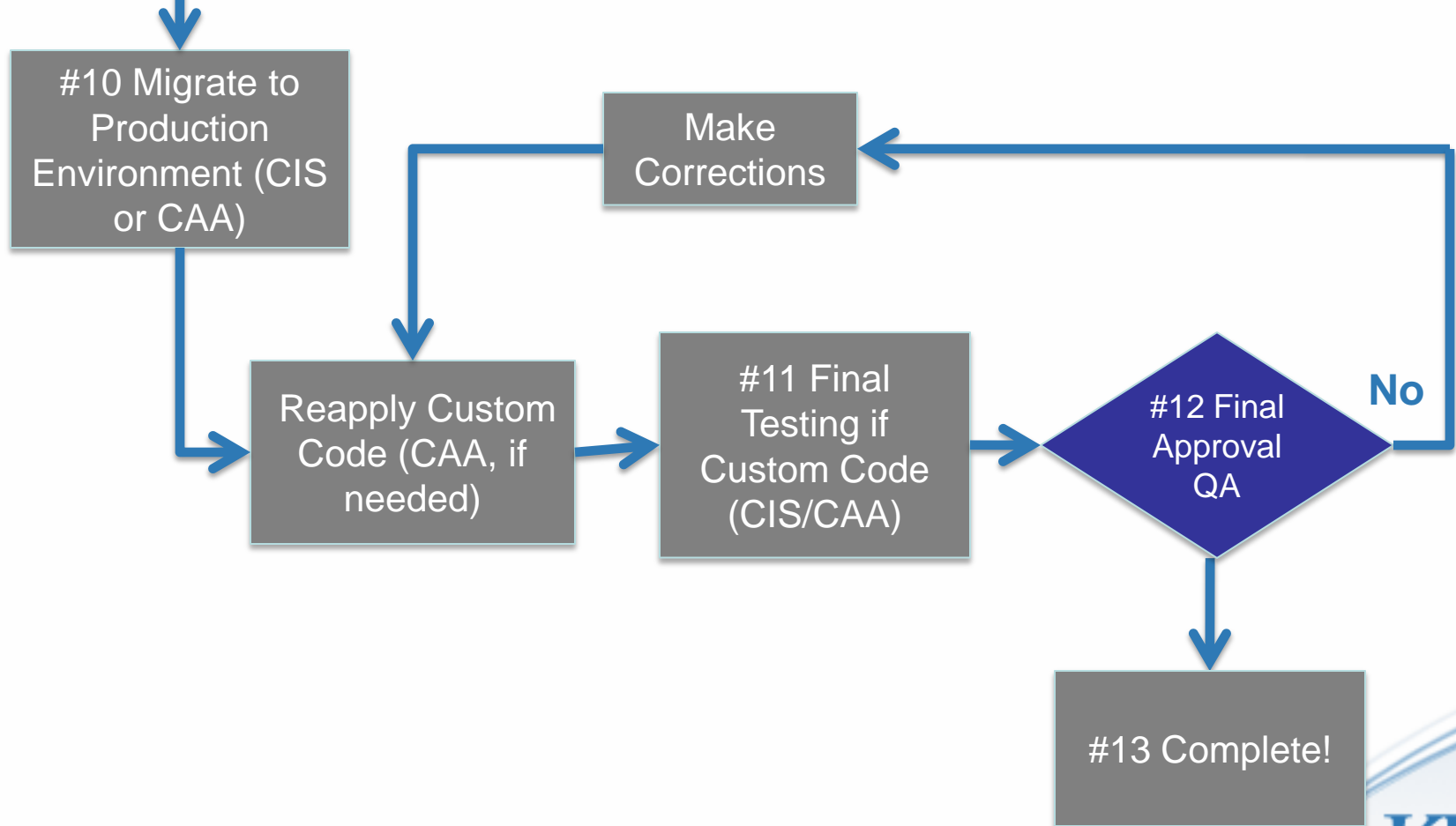
Phase 1: Designing Case Report Forms



Phase 2: Build, Test, Validate



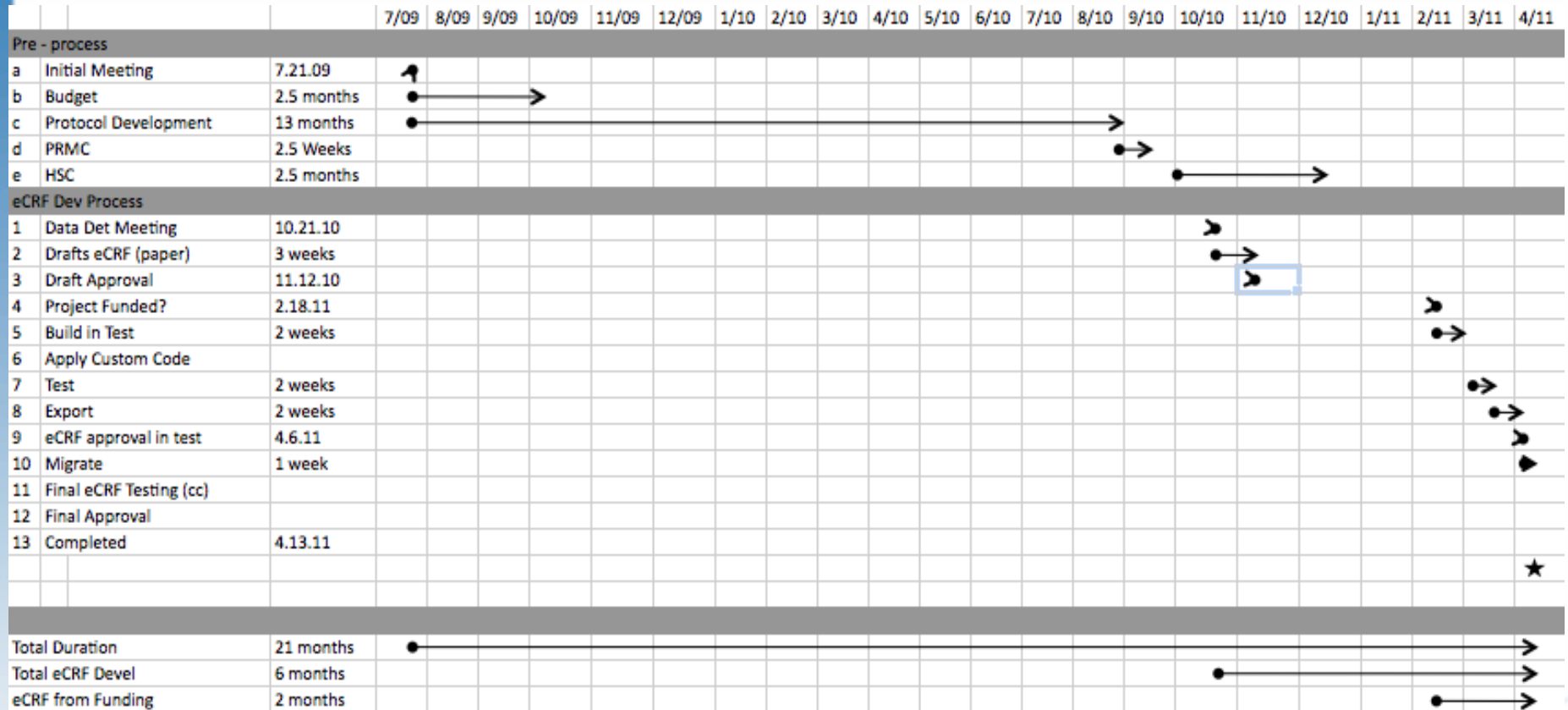
Phase 3: Deploy to Production



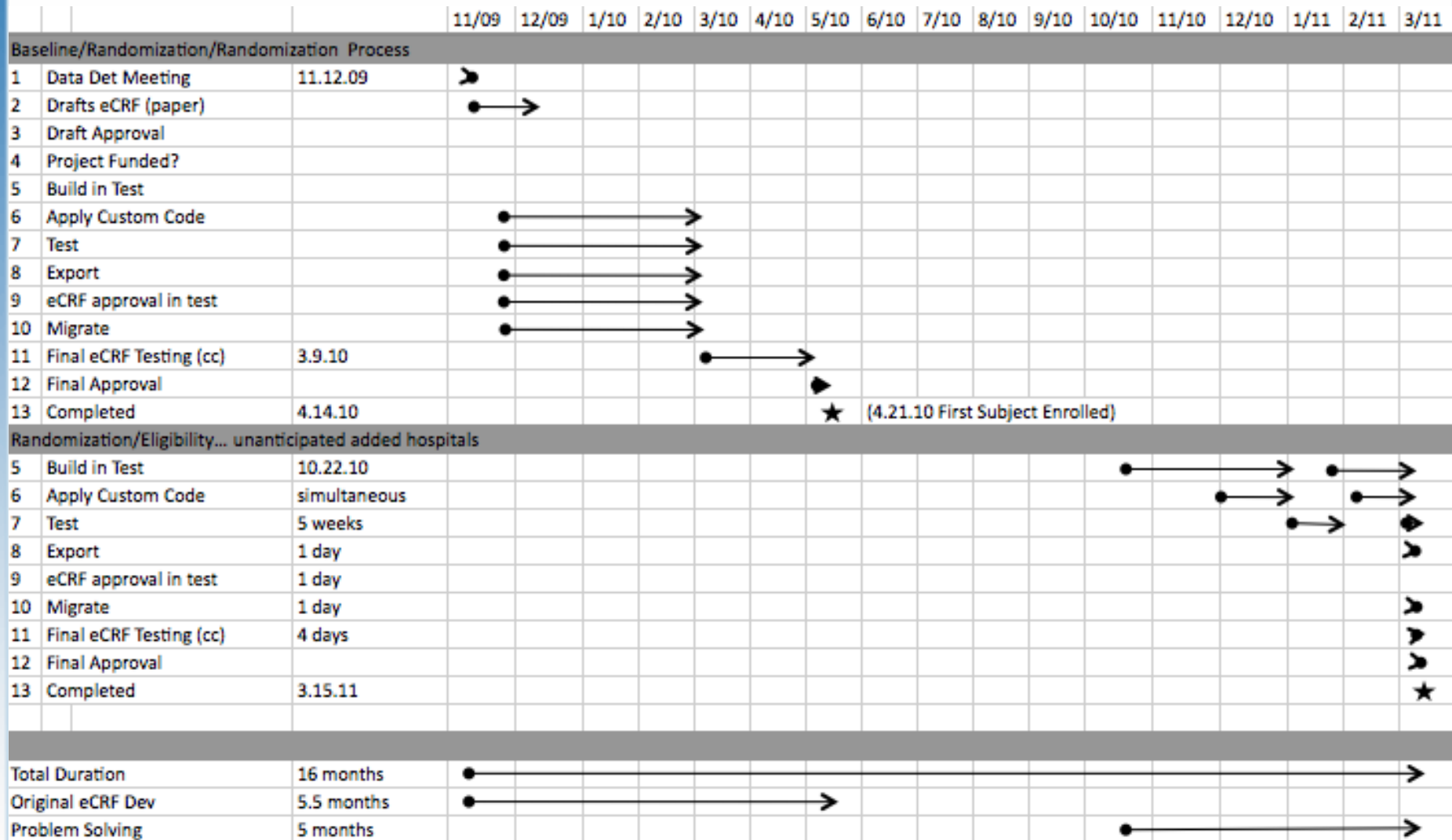
Private Grant with Existing Paper Forms

			10/10	11/10	12/10	1/11	2/11	3/11	4/11	
Pre - process										
a	Initial Meeting	10.26.10	↖							
b	Budget	1 day	↖							
c	Protocol Development									
d	PRMC									
e	HSC									
eCRF Dev Process										
1	Data Det Meeting									
2	Drafts eCRF (paper)									
3	Draft Approval									
4	Project Funded?	2.3.11				➤				
	Data Det Meeting	2.28.11					➤			
5	Build in Test	3 weeks					●→			
6	Apply Custom Code									
7	Test	4 weeks						●→		
8	Export	3 days							➤	
9	eCRF approval in test									
10	Migrate	1 day							➤	
11	Final eCRF Testing (cc)									
12	Final Approval									
13	Completed	4.26.11							★	
Summary										
Total Duration	6 months		●	→						➤
Total eCRF Devel	12 weeks					●	→			➤
eCRF from Funding	12 weeks					●	→			➤

Pharma sponsored IIT for Cancer Center



NIH R01 (Custom Randomization & Javascript)



Conclusions

- Coordination has improved
- Data dictionaries system derived; not paper
- Highlighted the unsustainable nature of customizing code unless critical to science
- Still being refined
 - Paper drafts versus build directly in system?
(especially for REDCap versus Velos)