A Streamlined Process for Electronic Case Report Form Development

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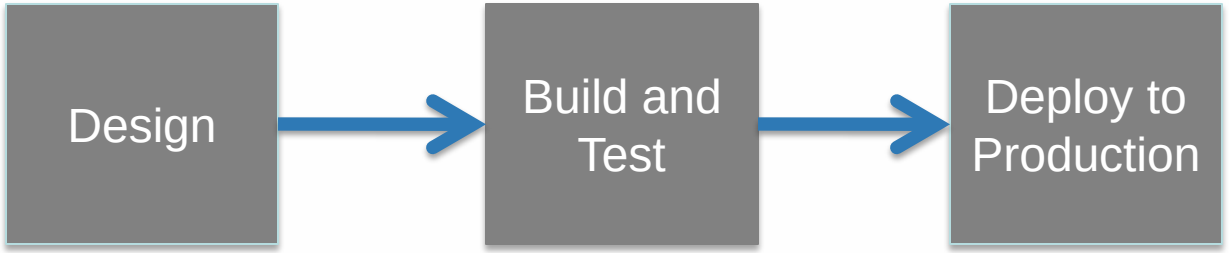
Outline

- 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

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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)

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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

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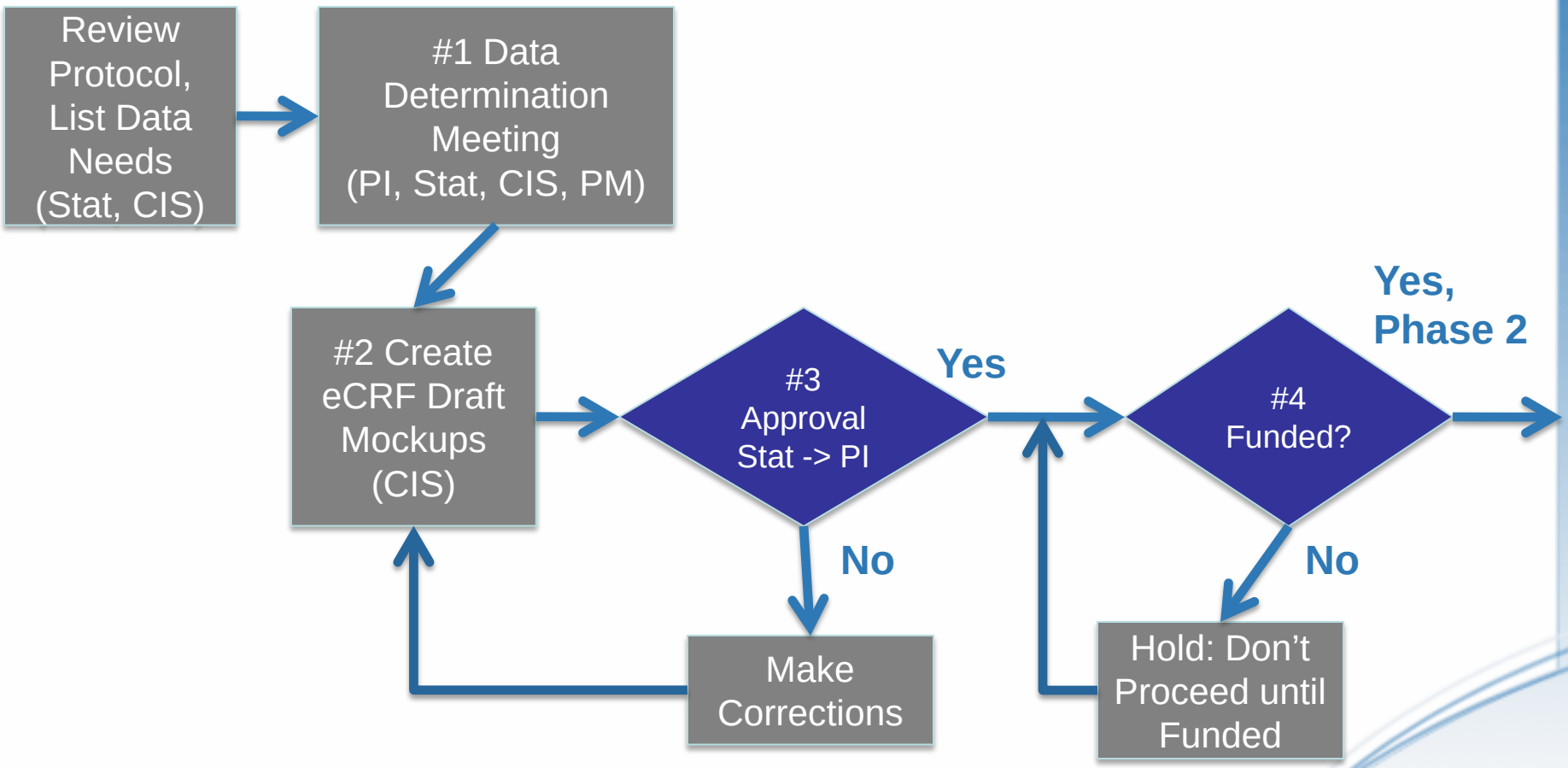
Phase 1: Designing Case Report Forms



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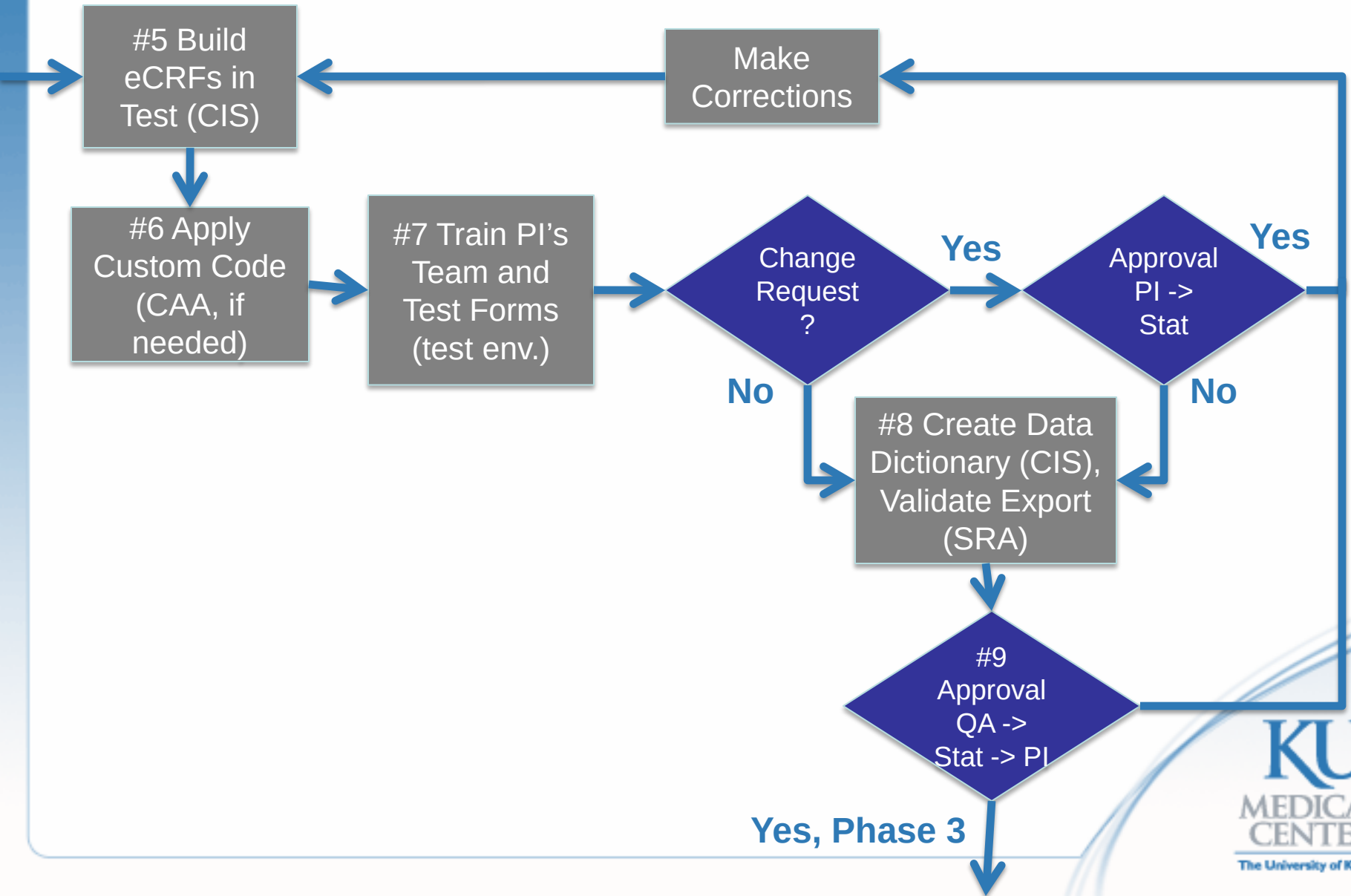
Phase 2: Build, Test, Validate



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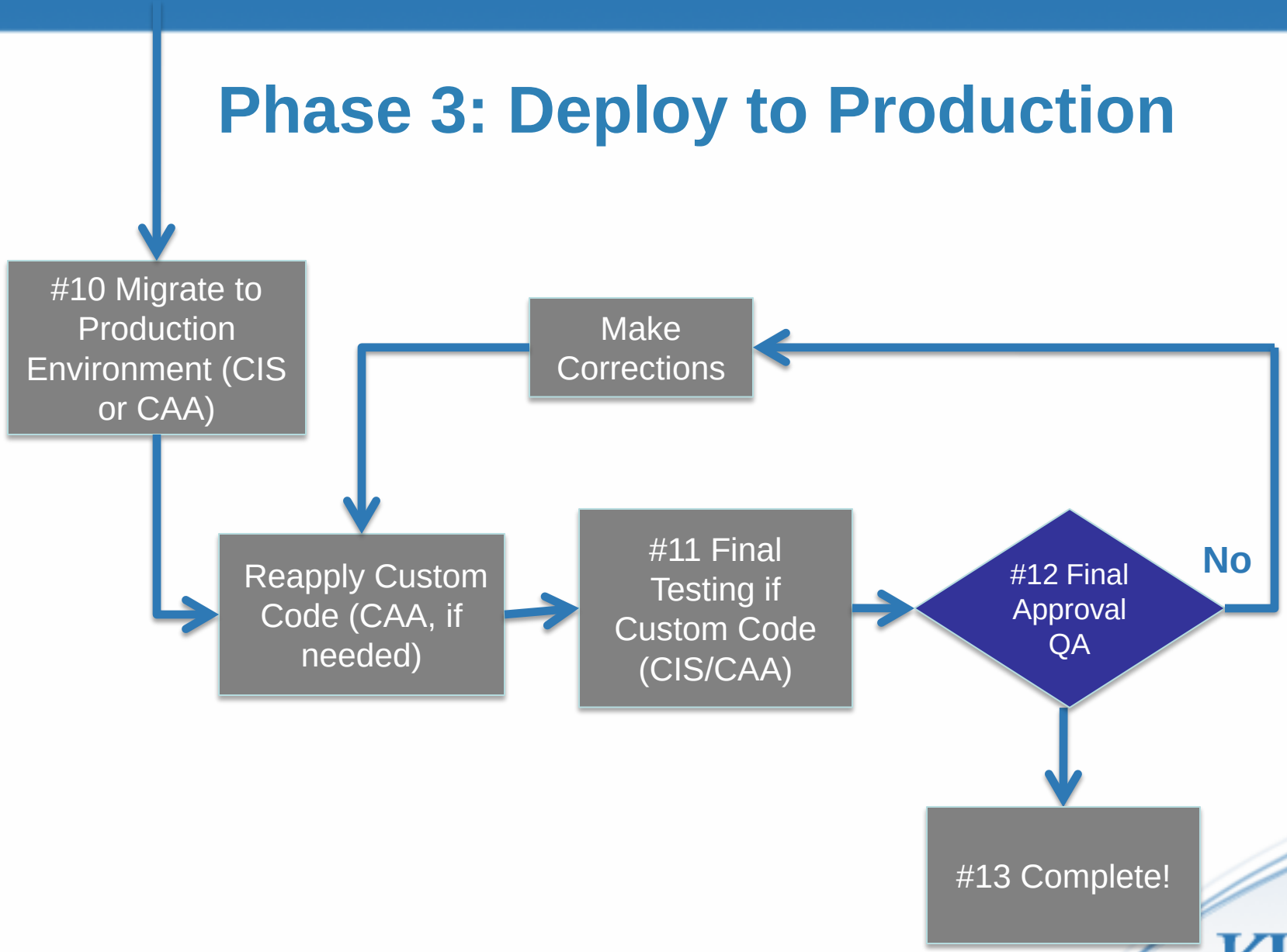
Phase 3: Deploy to Production



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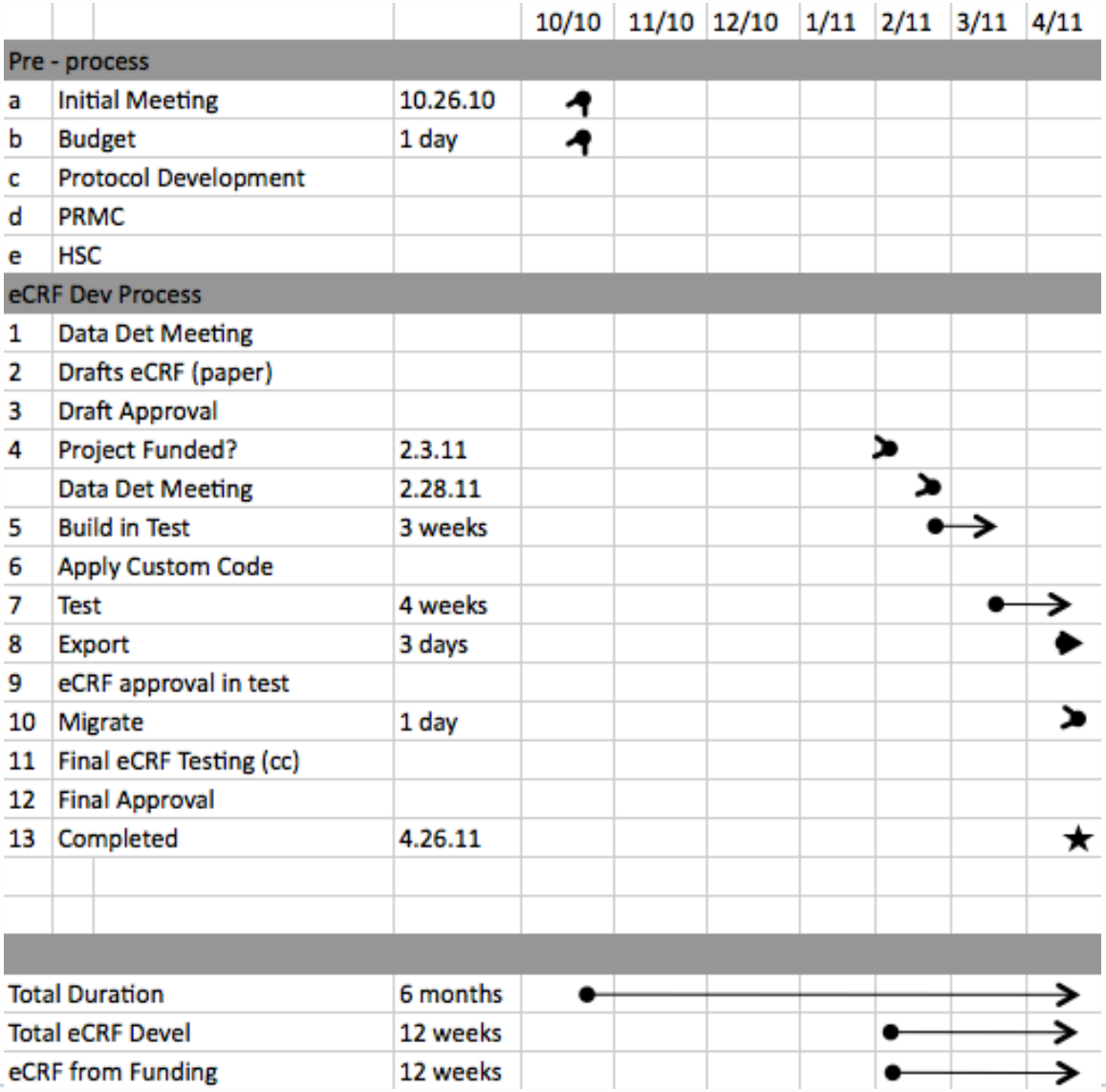
Private Grant with Existing Paper Forms



			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							
Total Duration		6 months							
Total eCRF Devel		12 weeks							
eCRF from Funding		12 weeks							

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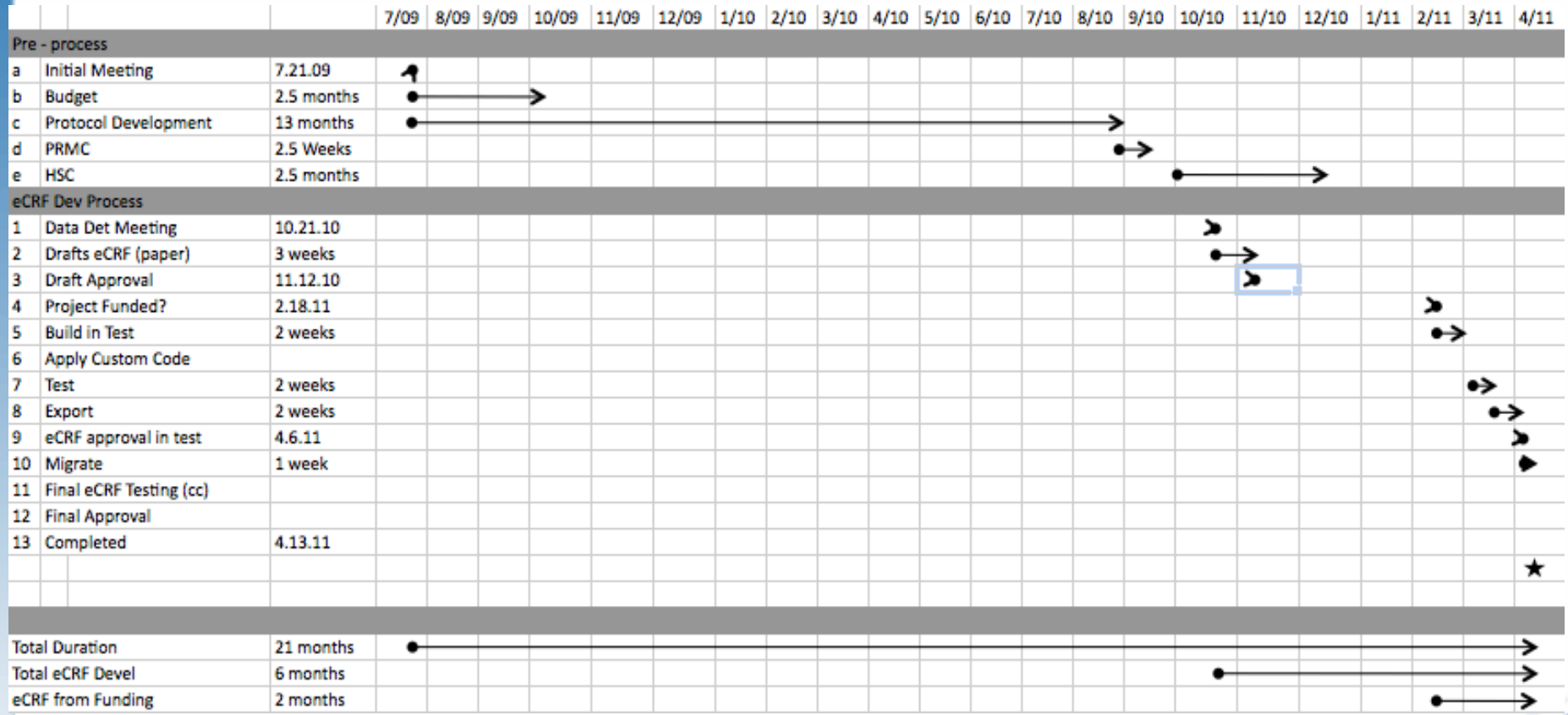
Pharma sponsored IIT for Cancer Center



			7/09	8/09	9/09	10/09	11/09	12/09	1/10	2/10	3/10	4/10	5/10	6/10	7/10	8/10	9/10	10/10	11/10	12/10	1/11	2/11	3/11	4/11
Pre - process																								
a	Initial Meeting	7.21.09																						
b	Budget	2.5 months																						
c	Protocol Development	13 months																						
d	PRMC	2.5 Weeks																						
e	HSC	2.5 months																						
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1	Data Det Meeting	10.21.10																						
2	Drafts eCRF (paper)	3 weeks																						
3	Draft Approval	11.12.10																						
4	Project Funded?	2.18.11																						
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7	Test	2 weeks																						
8	Export	2 weeks																						
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Total Duration		21 months																						
Total eCRF Devel		6 months																						
eCRF from Funding		2 months																						

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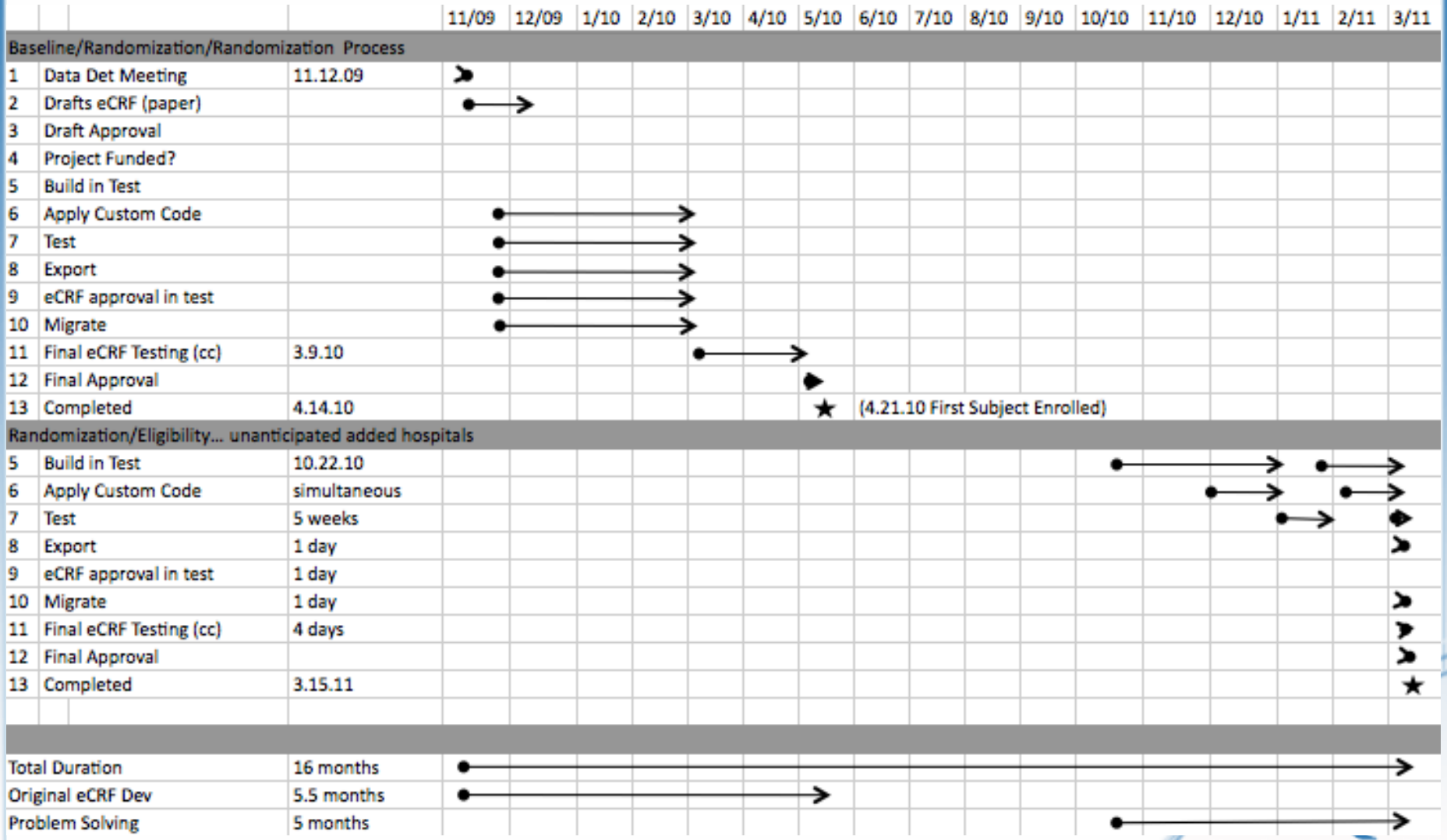
NIH R01 (Custom Randomization & Javascript)



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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)

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