



THE NATIONAL
CHILDREN'S
STUDY

Coordinating Center
Pre-proposal Conference
Warren Galke

National Institute of Child Health and
Human Development, NIH





Key Roles for Coordinating Center

- Provide Scientific Support to NCS Program Office
- Implement and support IMS
- Develop Detailed Study Documents in conjunction with NCS Program Office, Vanguard Centers
- Develop and implement QA/QC Program



Key Roles for Coordinating Center

- Develop and implement study coordination procedures
- Perform data management, processing, and analysis
- Support Vanguard Center's implementation of multi-stage probability sampling approach
- Serve as a Study Center for persons no longer living in places conveniently served by existing Vanguard or Study Centers

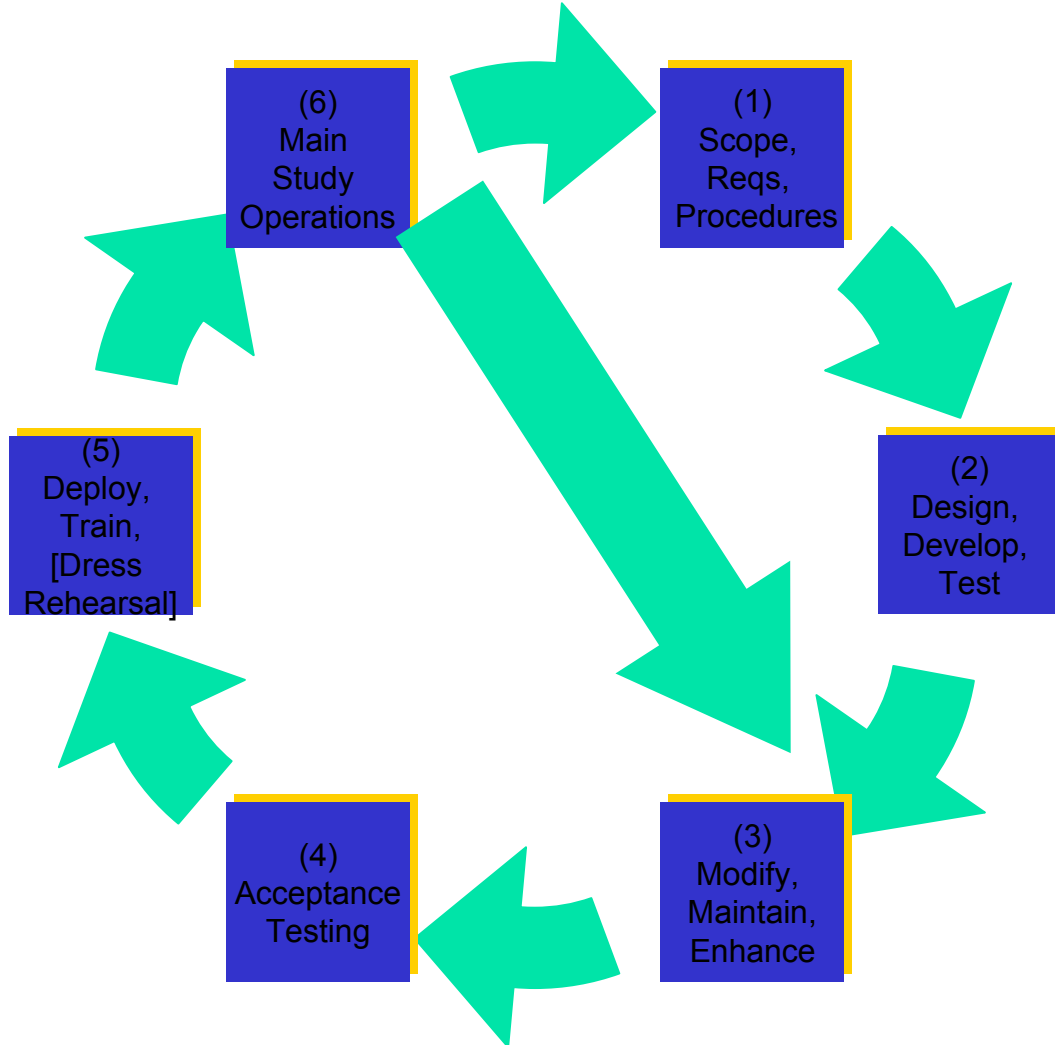


Scientific Support

- These activities will support the further development of the NCS
- The exact tasks will be specified by the NCS Project Officer
- Activities will range from preparing summaries of scientific meetings through the conduct of preliminary studies that will demonstrate feasibility of proposed data collection activities



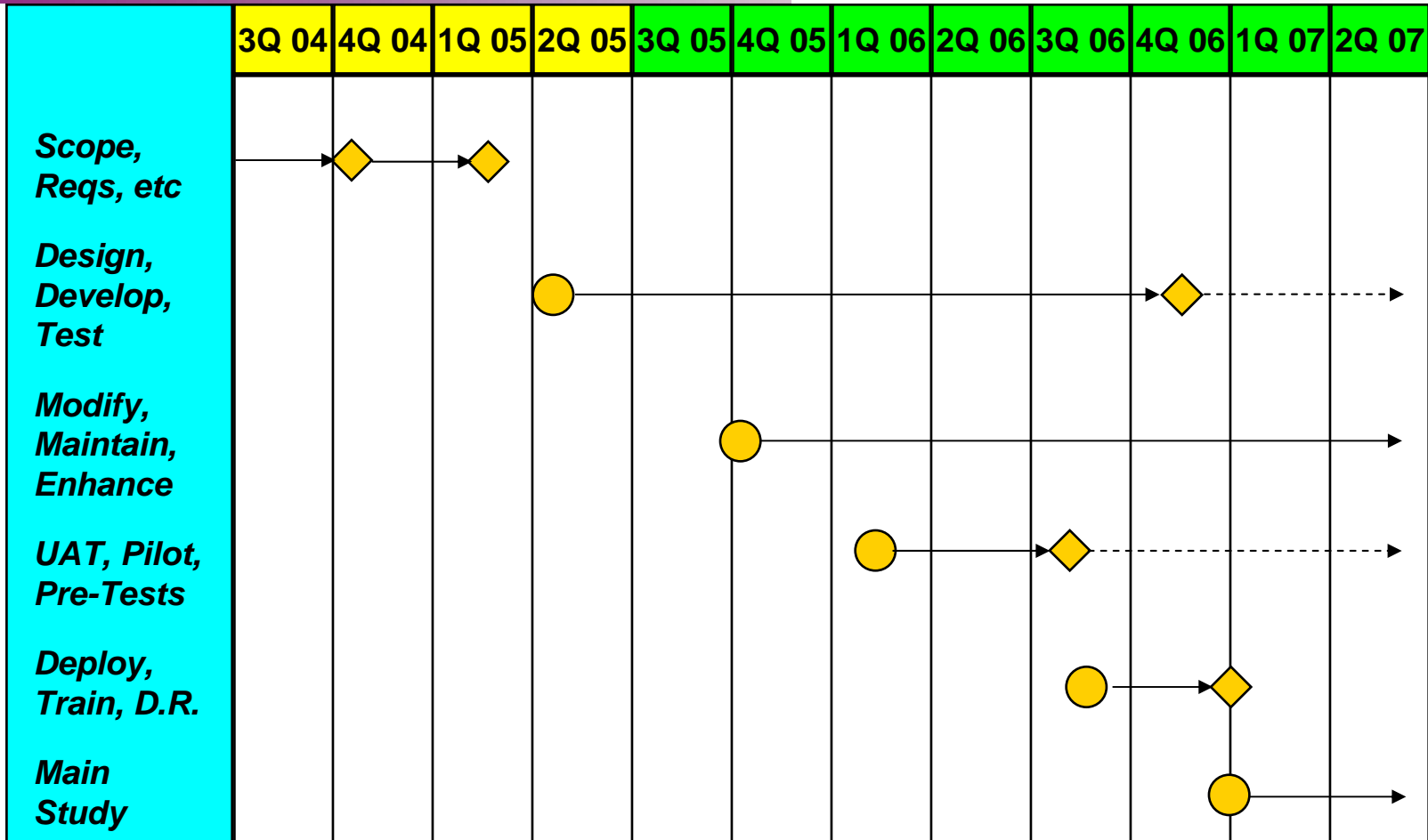
NCS IMS Lifecycle





Timeline

← IMS Contractor → IMS Contractor, Vanguard Centers, Coordinating Center →





Roles and Responsibilities

	Function				
	Scope, Requirements, Procedures	Design, Develop, Internal Test, Modify, Maintain, Enhance	User Acceptance Test	Pilot, Study Center Deployment, Training, Dress Rehearsal	Study Operations
Program Office	Produce, Approve	Approve	Approve	Approve	Approve, Use
Coordinating Center	Produce*, Coordinate*	Support, Coordinate	Conduct, Coordinate	Conduct, Coordinate	Use, Coordinate
IMS Contractor	Support	Produce	Support	Support	Support, Maintain, Refresh
Vanguard Centers	Support*	Support	Support	Support	Use

* - After Initial Protocol Development



Information Management System Status

Responsible Party

PO, IMS, CC, VC

PO, IMS, CC, VC

PO, IMS, CC

PO, IMS, CMEs

PO, IMS

PO, IMS

Delivery Date

1/07

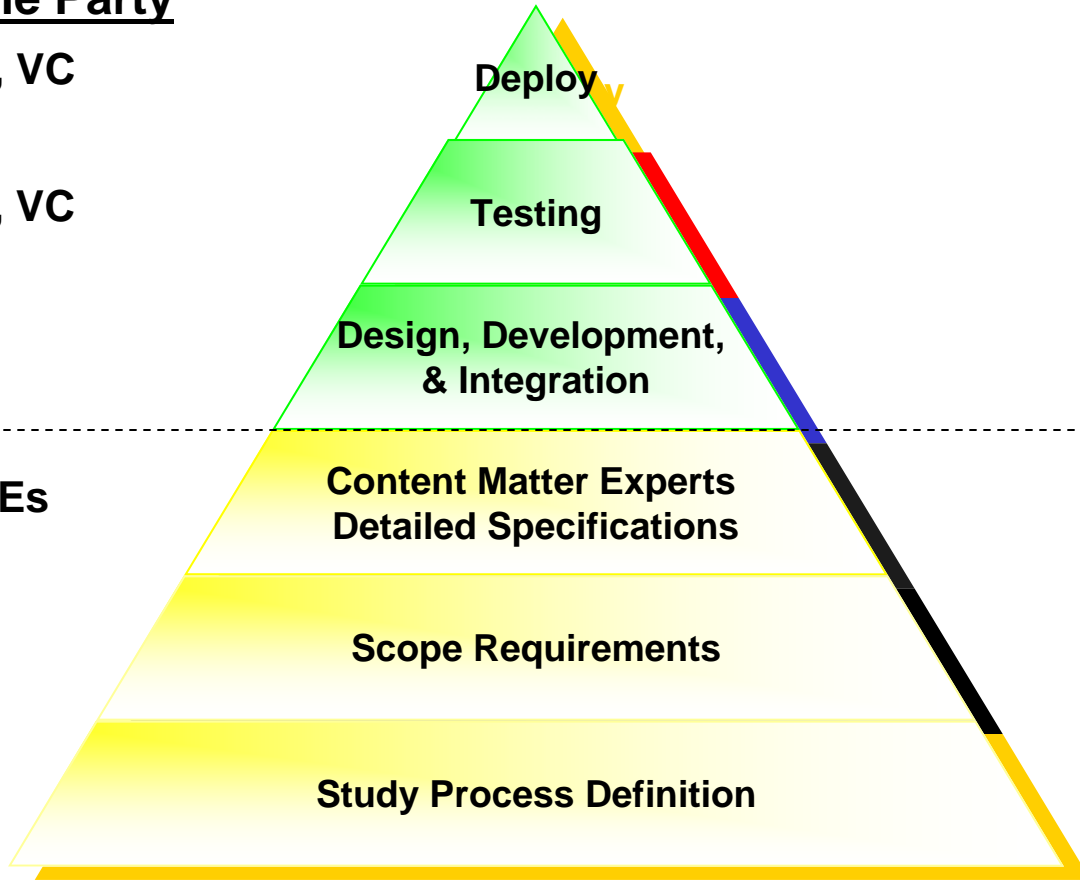
1/06 – 1/07

3/05 – 10/06

In Process

Completed

Completed

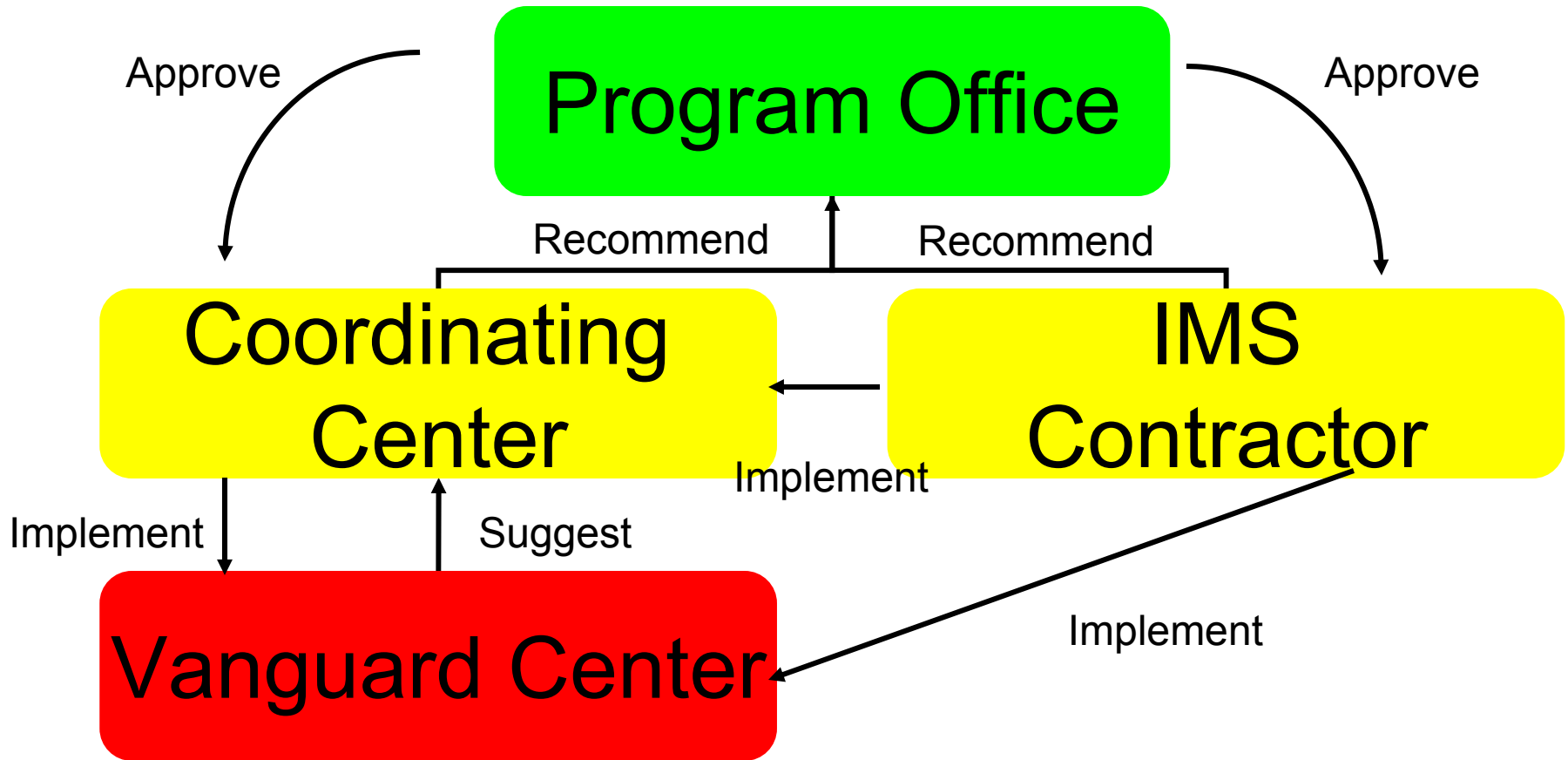


CC = Coordinating Center, CMEs = Content Matter Experts, IMS = IMS Contractor

PO = Program Office, VC = Vanguard Center



Change Management for IMS





Study Documents

- The Study Documents will include the Study Protocol, the detailed Operational Plans, and the Manual of Operating Procedures
- The development of the study documents will begin with a draft study protocol provided by the NCS Project Officer
- That draft study protocol will be developed by the NCS Program Office and will evolve from the study plan released with these RFPs



Study Documents (Con't)

- Two of the required Operational Plans reflect some of the unique aspects of the National Children's Study
- They are:
 - Scientific Outreach Program Plan
 - External Data Capture Plan



QA/QC Functions

- Quality Control Samples and Specimens
- QA/QC Oversight of laboratories and clinical testing facilities
- QA/QC Oversight of data collection activities
- QA/QC Activities for IMS performance
- Cooperation with outside party doing QC on data management procedures



Coordinating Center Serving as Study Center

- The Coordinating Center will serve as a study center under two scenarios:
 - An enrolled child moves away from the study center which enrolled him/her and is now not living near an existing Study Center
 - One of the Study Centers fail and therefore there is a need to cover the catchment area represented by that Study Center



Call Center

- The Coordinating Center will operate a 24 X 7 Call center to serve multiple needs:
 - As a communications link among the various participating study entities
 - As a communications link between Study participants and the Study
 - As a mechanism to remotely collect study data



CONTRACTING OFFICER CONTACTS

All can be reached at: NICHDCMB@MAIL.NIH.GOV 301-496-4611

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