Study Activation Project Plan

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Director, Coordination Services & Education

Study Activation Team

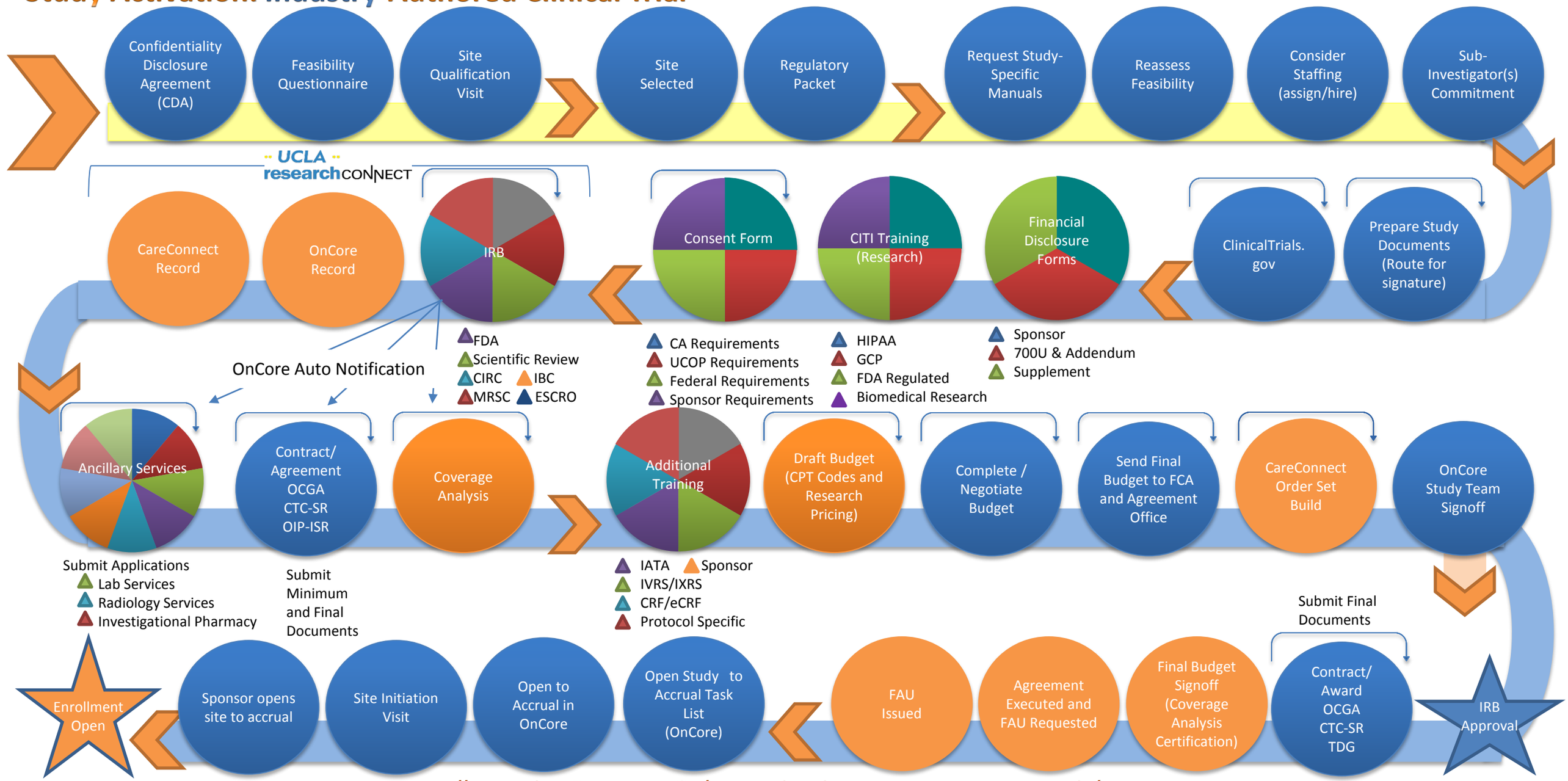
UCLA | Office of Clinical Research

Clinical and Translational Science Institute

Common Questions from Investigators

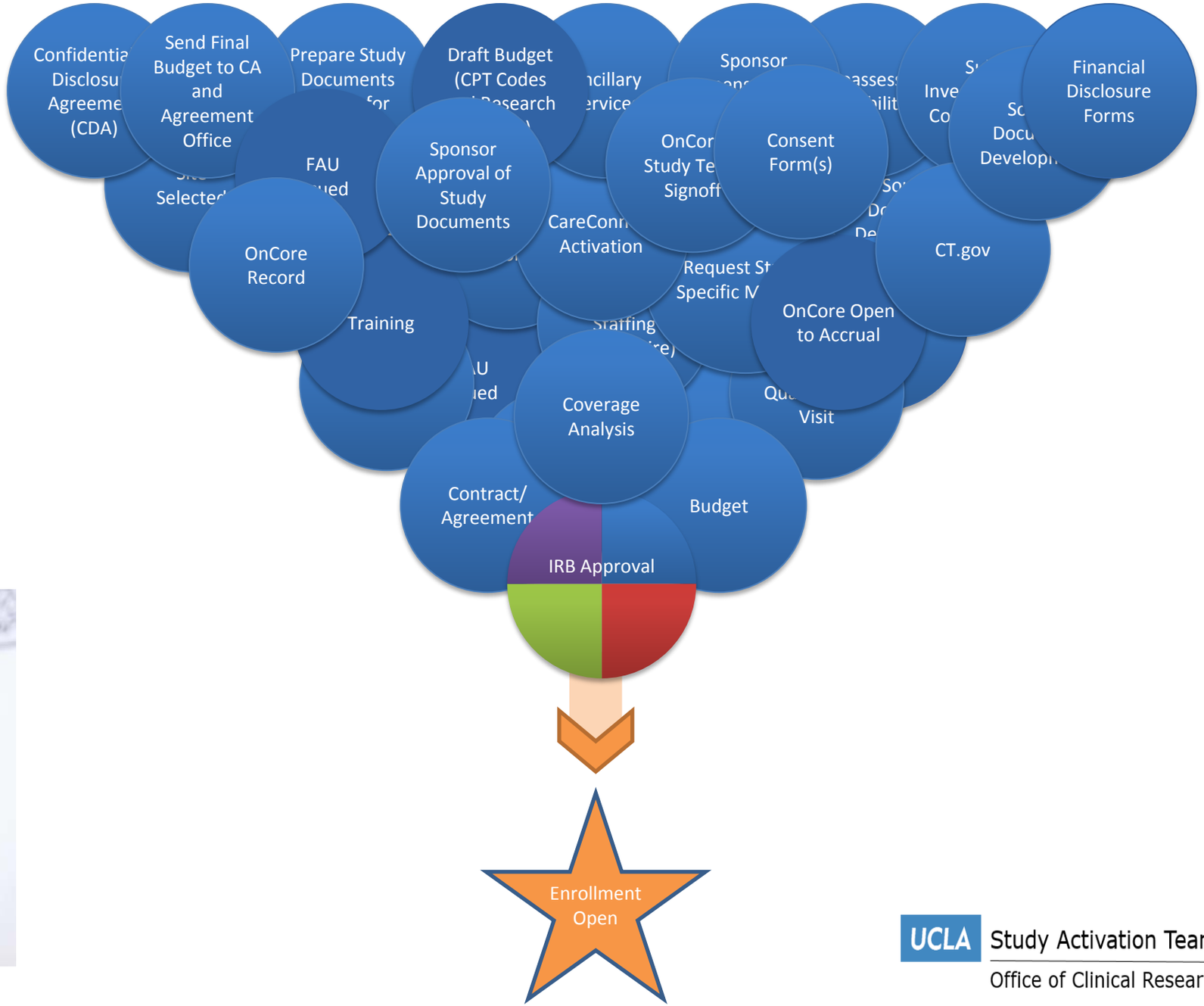
- How do I identify all of the study activation steps?
- How do I track the study activation process and stay on target?
- How can I minimize hurdles to study activation?
- Patients are waiting. When can I start screening?

Study Activation: Industry-Authored Clinical Trial



Illustrative Purposes Only – activation process not sequential

Study Activation
when there is no transparency



UCLA Study Activation Team
Office of Clinical Research

Study Activation
Key Considerations

UCLA Study Activation Team
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- Identify Steps
- Track Progress
- Minimize Hurdles
- Project Open to Enrollment Date

Study Activation Progress Plan - General

UCLA Study Activation Team
Office of Clinical Research

Project Plan General

UCLA Study Activation Team — Office of Clinical Research

IRB #:	12-001234
Sponsor:	Enterprise
Protocol #:	NCC1701
PI:	Picard
Short Title:	Enterprise NCC1701 Irumodic Syndrome
Last update:	7/11/18

IDENTIFY

CDA, Feasibility, Qualification
Site Selection Letter Received
UCLA Startup Letter to Sponsor
Full Reg Packet Received
ICF to Sponsor

Study Submissions:
IRB Application
Committee Applications
Ancillary Applications
Contract Min Docs
Budget Build Started

Budget & Contract Negotiations initiated with Sponsor

Budget Finalized
UCLA IRB Approval

Contract Executed

Site Initiation Visit
Open to Enrollment

Week 1 | **Week 4** | **Week 8-10** | **Week 11** | **Week 12-13**

SQV | Site Selection Finalized, Receive Regulatory Packet & Study Manual | Study Questions for PI & Sponsor to Provide | Develop ICF/Assent | Sponsor ICF Review

IRB Application Prep | IRB Review and Release of Notice of Approval | Approval

SRC Application Prep | SRC Review and Release of Notice of Approval

Other Committees | Other Committee Reviews and Release of Notice of Approval

Ancillary Application Prep | Ancillary Services Review and Release of Notice of Approval

Sponsor Budget Template Received

Contract (SOW) Template Recieved

Intake | Calendar Build | Coverage Analysis | Coding & Research Pricing | Budget Out | Add Admin Costs to Budget Out | Budget Negotiation | Budget In | Research Quality | Budget Signoff | Study Team Signoff | Research Quality | Final Budget Signoff

Min Docs Submitted | Contract Review | Contract Negotiations | Final Docs Submitted | Contract Finalized | Contract Routed for PI Signature | Contract Signed | Fund # Issued

CareConnect (EHR) SmartSet Build

Requisition Forms Available

Open To Accrual Signoff

CareConnect Activation

Regulatory Document Collection, Training Completion, Clinical/Procedure Unit In-Service, Sponsor Requirements for Site Readiness Fullfilled | Site Readiness | SIV | Spon. Auth

Target: Rapid Study Startup of Industry Supported studies < 90 days from IRB submission to OnCore Open to Accrual

Tip: A full regulatory packet must include protocol, sponsor ICF template, final or at least functional drafts of study manuals (i.e., lab manual, pharmacy manual, radiology manual, manual of operations, etc.). These documents are required for IRB new study application, ancillary application submissions and budget development.

LEGEND: ICF = Informed Consent; RQ = Research Quality; ST = Study Team; CC = CareConnect; FB = Final Budget; OTA = Open to Accrual (OnCore Protocol Status); SQV = Site Qualification Visit; SIV = Site Initiation Visit

Study Activation Progress Plan - Milestones

UCLA Study Activation Team
Office of Clinical Research

Project Plan with Critical Study Startup Milestones

IRB #:	12-001234
Sponsor:	Enterprise
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Short Title:	Enterprise NCC1701 Irumodic Syndrome
Last update:	7/11/18

Progress Tracker

#	CONTRACT	DATE	DONE
0	Agreement received:	2/1/18	✓
1	Full Regulatory Packet	2/1/18	✓
2	Minimum Documents:	2/3/18	✓
3	Redline Out:	2/16/18	✓
4	Terms Finalized:	3/30/18	✓
5	Final Documents:	4/8/18	✓
6	Contract sent to PI for Signature (Partially Executed)	4/9/18	✓
7	Contract sent to Sponsor for Signature (Partialy Executed)	4/12/18	✓
8	Contract Signed:	4/15/18	✓
29	Fund Issued:	4/18/18	✓

#	BUDGET	DATE	DONE
9	OnCore Record Created:	1/25/18	✓
10	Intake:	1/25/18	✓
11	OnCore Build:	2/1/18	✓
12	Ancillary Notifications:	1/28/18	✓
13	Submission to Ancillaries:	1/30/18	✓
14	Ancillary Notice of Approvals:	2/13/18	✓
15	Coverage Analysis:	2/15/18	✓
16	Coding:	2/18/18	✓
17	Budget Out:	2/20/18	✓
18	Budget In:	3/24/18	✓

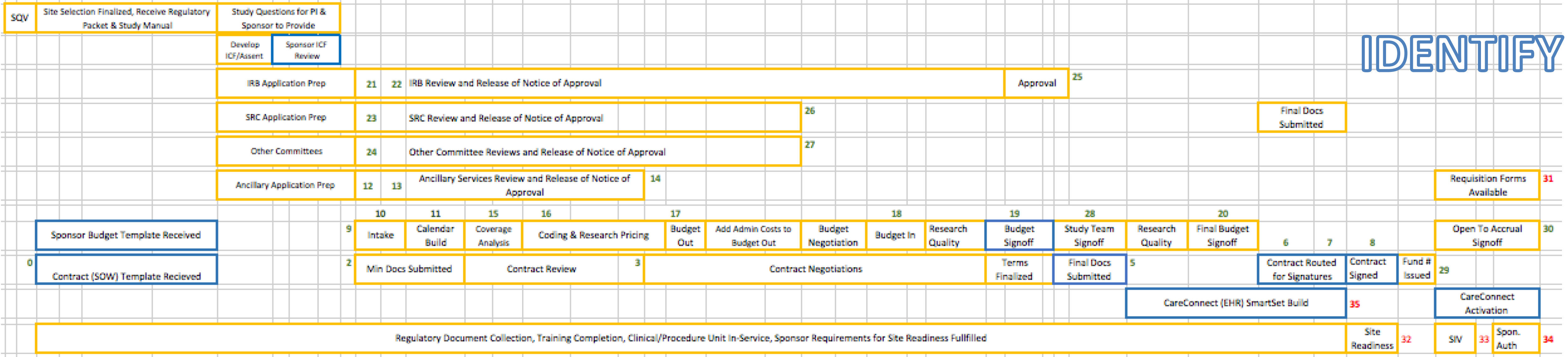
#	RESEARCH QUALITY	DATE	DONE
19	Budget Sign off:	3/31/18	✓
20	Final Budget Sign off:	4/6/18	✓

#	IRB	DATE	DONE
21	Pre-IRB Submission:	1/26/18	✓
22	IRB Submission:	3/1/18	✓
23	ISPRC-SRC Submission	1/26/18	✓
24	Committee Submissions:	1/26/18	✓
25	IRB Approval:	3/28/18	✓
26	ISPRC-SRC Approvals	2/23/18	✓
27	Committee Approvals:	2/23/18	✓

#	FINAL STEPS	DATE	DONE
28	Study Team Sign off:	4/3/18	✓
30	Open to Accrual:	4/21/18	✓
31	Ancillary Requisitions:		✗
32	Site Readiness		✗
33	Site Initiation Visit		✗
34	Sponsor Authorization		✗
35	CC SmartSet Build		✗

TRACK

IDENTIFY


SQV
Site Selection Finalized, Receive Regulatory Packet & Study Manual
Study Questions for PI & Sponsor to Provide
Develop ICF/Assent
Sponsor ICF Review
IRB Application Prep
21
22
IRB Review and Release of Notice of Approval
Approval
25
SRC Application Prep
23
SRC Review and Release of Notice of Approval
26
Final Docs Submitted
Other Committees
24
Other Committee Reviews and Release of Notice of Approval
27
Ancillary Application Prep
12
13
Ancillary Services Review and Release of Notice of Approval
14
Requisition Forms Available
31
Sponsor Budget Template Received
9
Intake
10
Calendar Build
11
Coverage Analysis
15
Coding & Research Pricing
16
Budget Out
17
Add Admin Costs to Budget Out
Budget Negotiation
Budget In
18
Research Quality
Budget Signoff
19
Study Team Signoff
28
Research Quality
Final Budget Signoff
20
Open To Accrual Signoff
30
0
Contract (SOW) Template Recieved
2
Min Docs Submitted
Contract Review
3
Contract Negotiations
Terms Finalized
Final Docs Submitted
5
6
7
8
Contract Routed for Signatures
Contract Signed
Fund # Issued
29
CareConnect (EHR) SmartSet Build
35
CareConnect Activation
Regulatory Document Collection, Training Completion, Clinical/Procedure Unit In-Service, Sponsor Requirements for Site Readiness Fullfilled
Site Readiness
32
SIV
33
Spon. Auth
34

LEGEND: ICF = Informed Consent; RQ = Research Quality; ST = Study Team; CC = CareConnect; FB = Final Budget; OTA = Open to Accrual (OnCore Protocol Status); SQV = Site Qualification Visit; SIV = Site Initiation Visit

Study Activation Progress Plan - Report

UCLA Study Activation Team
Office of Clinical Research

Study Activation Progress Report

UCLA Study Activation Team, Office of Clinical Research

IRB #:	12-001234
Sponsor:	Enterprise
Protocol #:	NCC1701
PI:	Picard
Short Title:	Enterprise NCC1701 Inumodic Syndrome

Instructions: Update the light blue cells in the dark blue columns as tasks are started, submitted and completed/approved to track study activation progress in real time. The grey cells are automatically updated to reflect the current data imported into the oncore tab.

Target IRB Submission:	2/1/18		
Target Open Enrollment:	5/3/18	13.0	wks
Full Regulatory Packet:	1/1/18		
Actual IRB Submission:	3/1/18		
Projected Open Enrollment:	6/11/18	18.6	wks

Legend	
RA: Review and Approval	Calculation
P: Process	Actual Data from OnCore
D: Document	Manual Entry
ST: Study Team	Has Dependencies

Study Startup Tasks			Target Dates		Actual Dates based on OnCore Data		Task Progress					
Milestone #	Task Type	Description	Start Date (Submission Date)	Completion Date (Approval Date)	Start Date (Submission Date)	Completion Date (Approval Date)	Not initiated	In progress	Completed	Overall	PI Action Required	Note
		IRB and Committee Approvals	Submit to ancillaries within 1 wk of IRB									
25	RA	New Study IRB Approval	2/1/18	5/24/18	3/1/18	3/28/18			x	✓		
26	RA	Internal Scientific Review Approval	2/4/18	3/4/18	1/26/18	2/23/18			x	✓		
27	RA	Medical Radiation Safety Approval	2/4/18	3/4/18	3/1/18	2/23/18			x	✓		
27	RA	Conflict of Interest Review Approval	2/4/18	3/4/18	1/26/18	2/23/18			x	✓		
27	RA	Institutional Biosafety Approval	2/4/18	3/18/18	1/26/18	3/9/18			x	✓		
27	RA	Embryonic Stem Cell Research Oversight	2/4/18	3/18/18	1/26/18	3/9/18			x	✓		
27	RA	Value Analysis Approval	2/4/18	3/4/18	1/26/18	2/23/18			x	✓		
27	RA	Clinical Engineering Approval or Acceptance	2/4/18	3/4/18	1/26/18	2/23/18			x	✓		

Target Turnaround		Actual Turnaround		±
Target Turnaround		Actual Turnaround		
16	weeks	4	weeks	-8
4	weeks	4	weeks	-1
4	weeks	-1	weeks	-1
4	weeks	4	weeks	-1
6	weeks	6	weeks	-1
6	weeks	6	weeks	-1
4	weeks	4	weeks	-1
4	weeks	4	weeks	-1

Responsibility Matrix and Resources								
Responsible For Task Start	Task Started When	Task Completed when:	Study Team Contact	Study Team Contribution (Tips and Best Practices)	UCLA Office Acronym	UCLA Office Full Name	UCLA Office Contact (email address and website)	Note
Study Team vs. UCLA Office								
Study Team	Submission of New	IRB issues aprpoval notice	name of	Respond to IRB	OHRPP	Office of Human	Owner (IRB Staff) named on	
Study Team	SRC will email if	SRC issues approval notice	name of	Respond to SRC	CTSI SRC (non-	Scientific Review	ctsisrc@mednet.ucla.edu	
Study Team	Section 8.11	MRSC issues approval	name of	Connect with	MRSC	Medical Radiation	mrsc@mednet.ucla.edu	
Study Team	Submission of	CIRC issues letter with final	name of	CIRC meets once a	CIRC	Conflict of Interes	circ@mednet.ucla.edu	
Study Team	Submission of new	IBC issues approval notice	name of	Send blank IBC	IBC	Institutional Bio	ibc@mednet.ucla.edu	
Study Team	Submission of	ESCRO issues approval	name of	Confirm with ESCRO if	ESCRO	Embryonic Stem	escro@mednet.ucla.edu	
Study Team	Submission of	VAC issues approval notice	name of	Required if	VAC	Value Analysis Co	vac@mednet.ucla.edu	
Study Team	Email summary of	Clinical Engineering issues	name of		CE	Clinical Engineeri	vemilian@mednet.ucla.edu	

IDENTIFY

TRACK

MINIMIZE HURDLES

Study Activation Progress Plan - Report

UCLA Study Activation Team
Office of Clinical Research

IDENTIFY STEPS

Study Activation Progress Report

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		IRB and Committee Approvals	Submit to ancillaries within 1 wk of IRB	
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27	RA	Clinical Engineering Approval or Acceptance	2/4/18	3/4/18

Study Activation Progress Plan - Report

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Office of Clinical Research

TRACK PROGRESS

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Legend	
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Actual Dates based on OnCore Data		Task Progress						Target Turnaround		Actual Turnaround		
Start Date (Submission Date)	Completion Date (Approval Date)	Not initiated	In progress	Completed	Overall	#1 Action Required	Note	Target Turnaround		Actual Turnaround		=
3/1/18	3/28/18			x	✓			16	weeks	4	weeks	-8
1/26/18	2/23/18			x	✓			4	weeks	4	weeks	-1
3/1/18	2/23/18			x	✓			4	weeks	-1	weeks	-1
1/26/18	2/23/18			x	✓			4	weeks	4	weeks	-1
1/26/18	3/9/18			x	✓			6	weeks	6	weeks	-1
1/26/18	3/9/18			x	✓			6	weeks	6	weeks	-1
1/26/18	2/23/18			x	✓			4	weeks	4	weeks	-1
1/26/18	2/23/18			x	✓			4	weeks	4	weeks	-1

Study Activation Progress Plan - Report

UCLA Study Activation Team
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MINIMIZE HURDLES

Responsibility Matrix and Resources

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Study Team	Submission of new	IBC issues approval notice	name of	Send blank IBC	IBC	Institutional Bios	ibc@mednet.ucla.edu	
Study Team	Submission of	ESCRO issues approval	name of	Confirm with ESCRO if	ESCRO	Embryonic Stem C	escro@mednet.ucla.edu	
Study Team	Submission of	VAC issues approval notice	name of	Required if	VAC	Value Analysis Co	vac@mednet.ucla.edu	
Study Team	Email summary of	Clinical Engineering issues	name of		CE	Clinical Engineeri	vemilian@mednet.ucla.edu	

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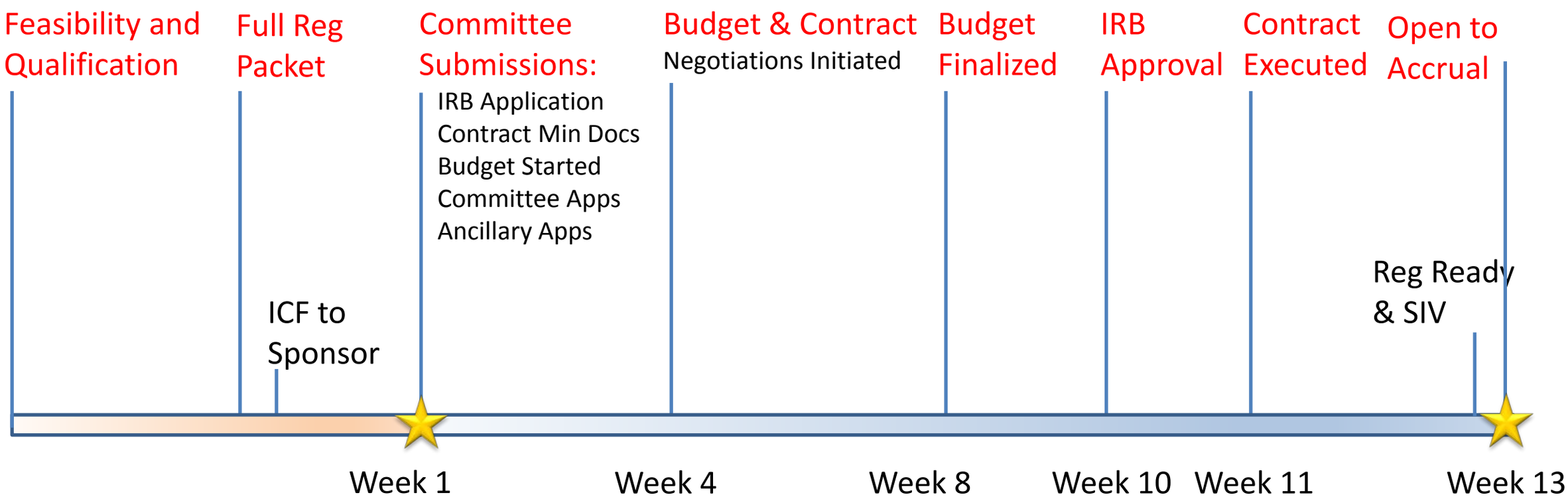
Project Open to Enrollment Date

Study Activation Team – 90-day Study Activation Model

UCLA Study Activation Team
Office of Clinical Research

Study Activation in 90 Calendar Days

From IRB Submission to Open to Accrual



Further Development

1. Development phase: Define turn around times for all tasks
2. Testing phase: test functionality using expected cases
3. Pilot phase: track startup timelines of real studies
4. Use project plan to inform dashboards and analytics
5. Align with questionnaire to enable self-service Project Plans
6. Adapt to other workflows
    - HemOnc
    - IRB Reliance
    - Investigator Initiated Studies

THANK YOU

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