

# Clinical Research Improvement in Systems and Processes

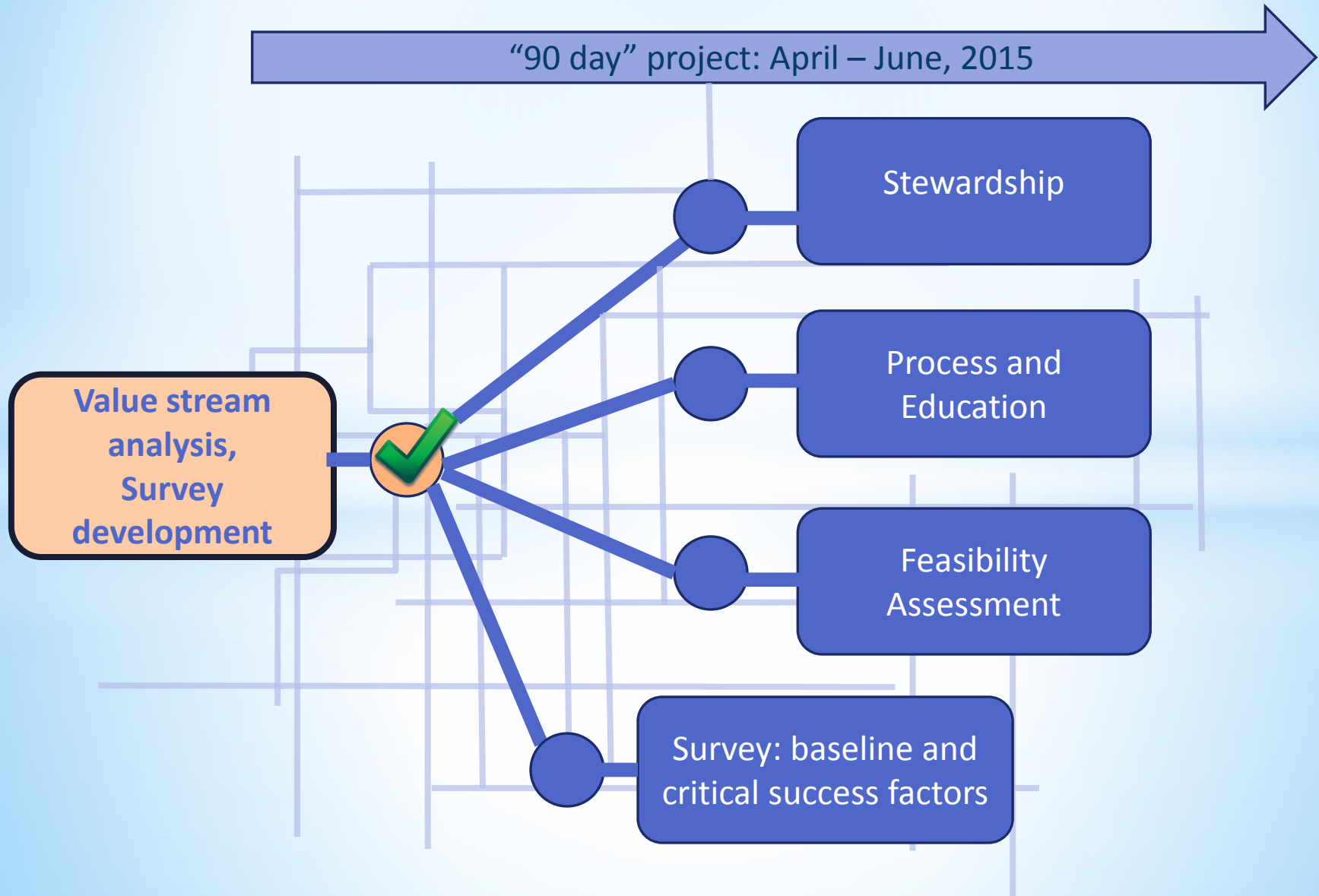
June 19, 2015



Known



# The map of our journey



# Accomplishments *and Agenda*

## Stewardship

- Expanded value stream analysis, increased visibility which allows to see waste
- Concept of our target condition

## Process and Education

- Framework for analysis and specification
- Opportunities for process integration

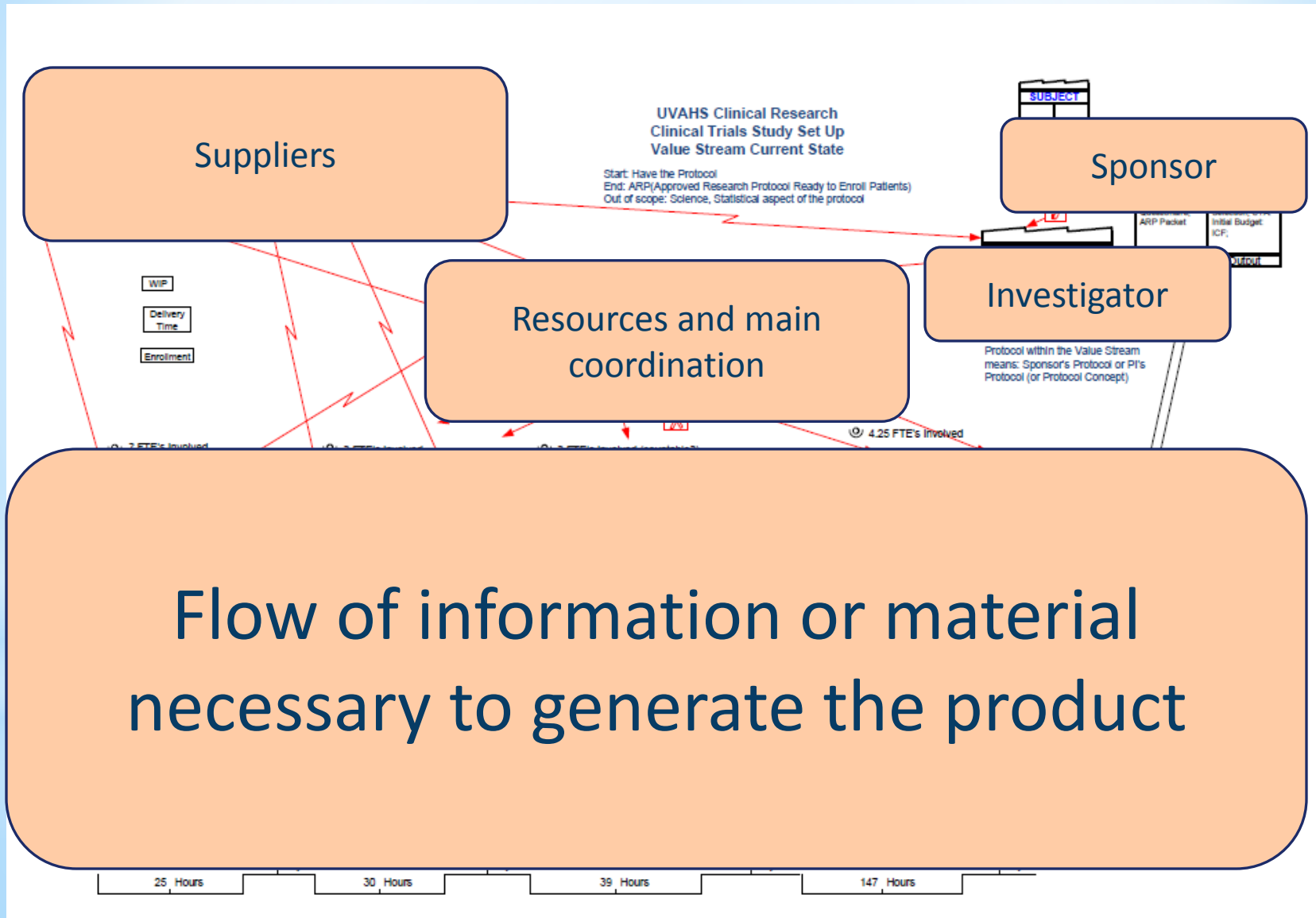
## Feasibility Assessment Concept

- Initial proposal for a process and specification supporting the goal
- Testing the concept

## Survey Analysis

## Next steps

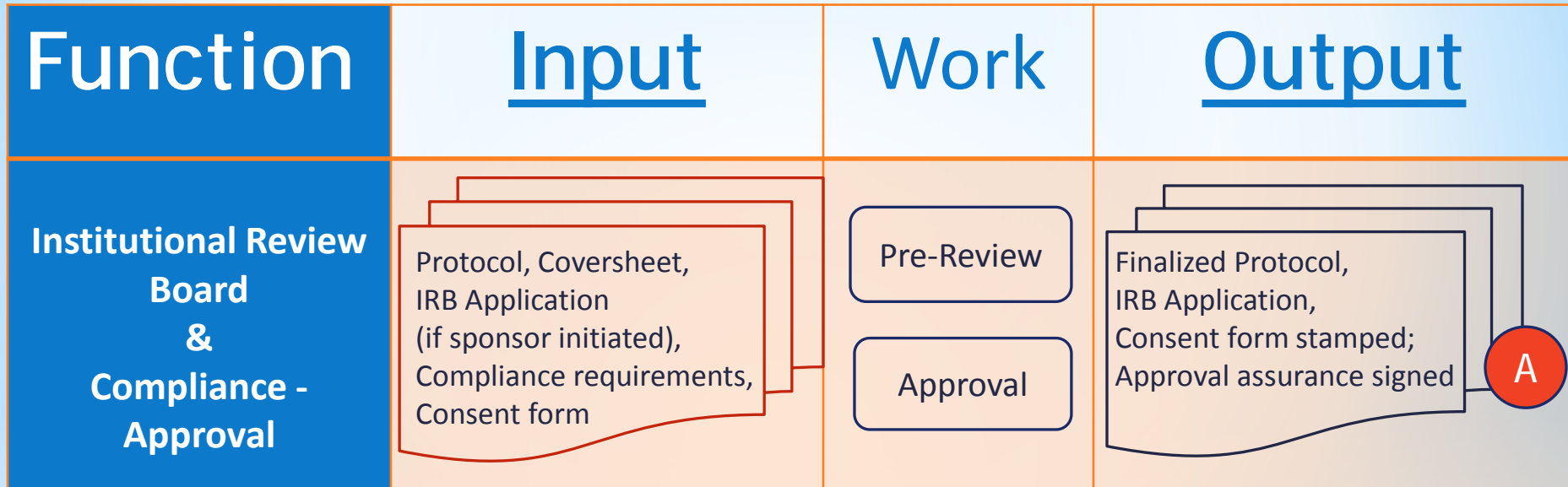
# Value stream map



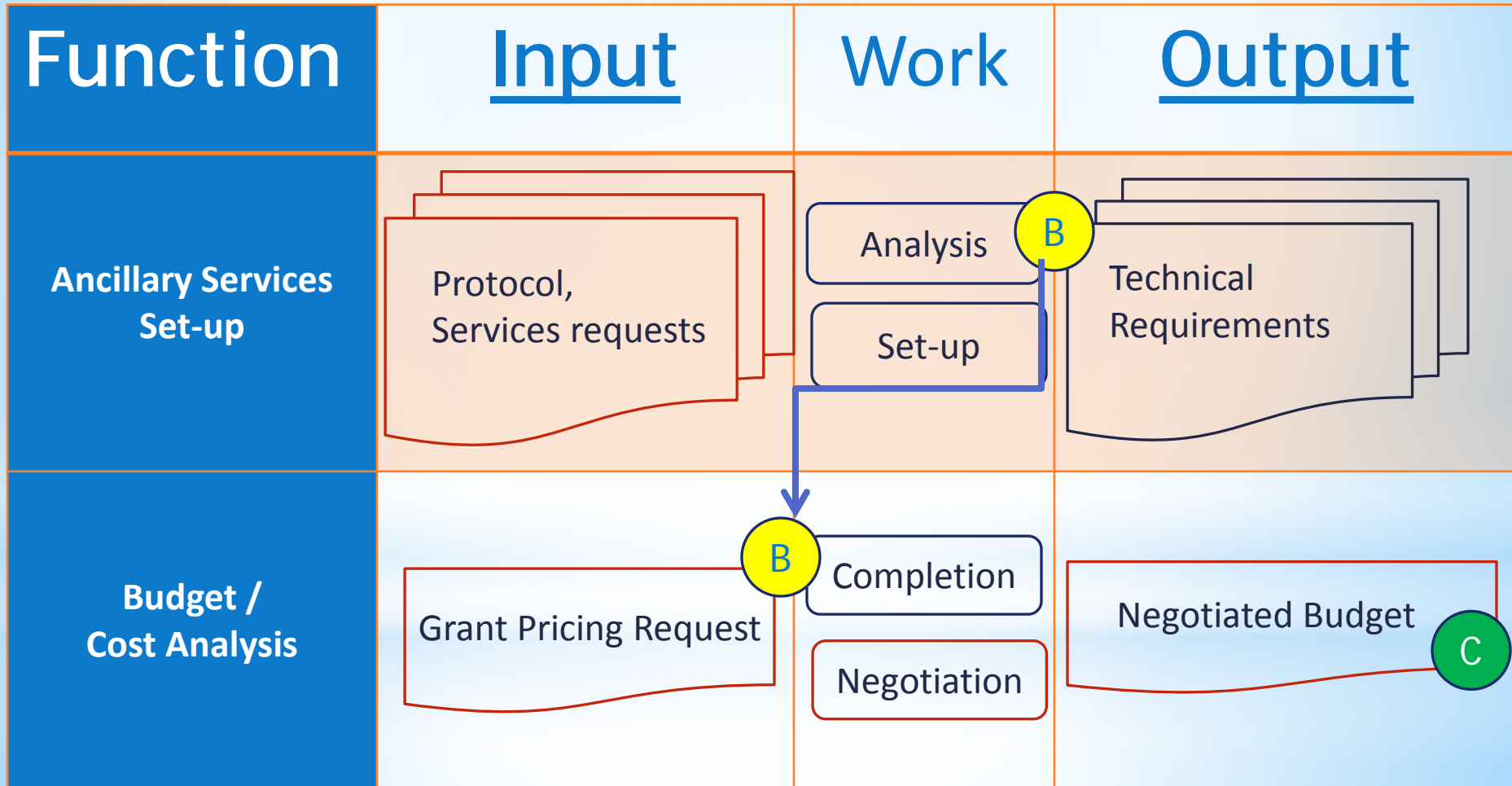
# Flow of information or material necessary to generate the product

<b>Function</b>	<u><b>Input</b></u>	<b>Work</b>	<u><b>Output</b></u>
<b>Institutional Review Board and Compliance approval</b>			
<b>Ancillary Services Set-up</b>			
<b>Budget / Cost Analysis</b>			
<b>Billing Set-up</b>			
<b>Contract Execution</b>			
<b>PTAOs Creation</b>			

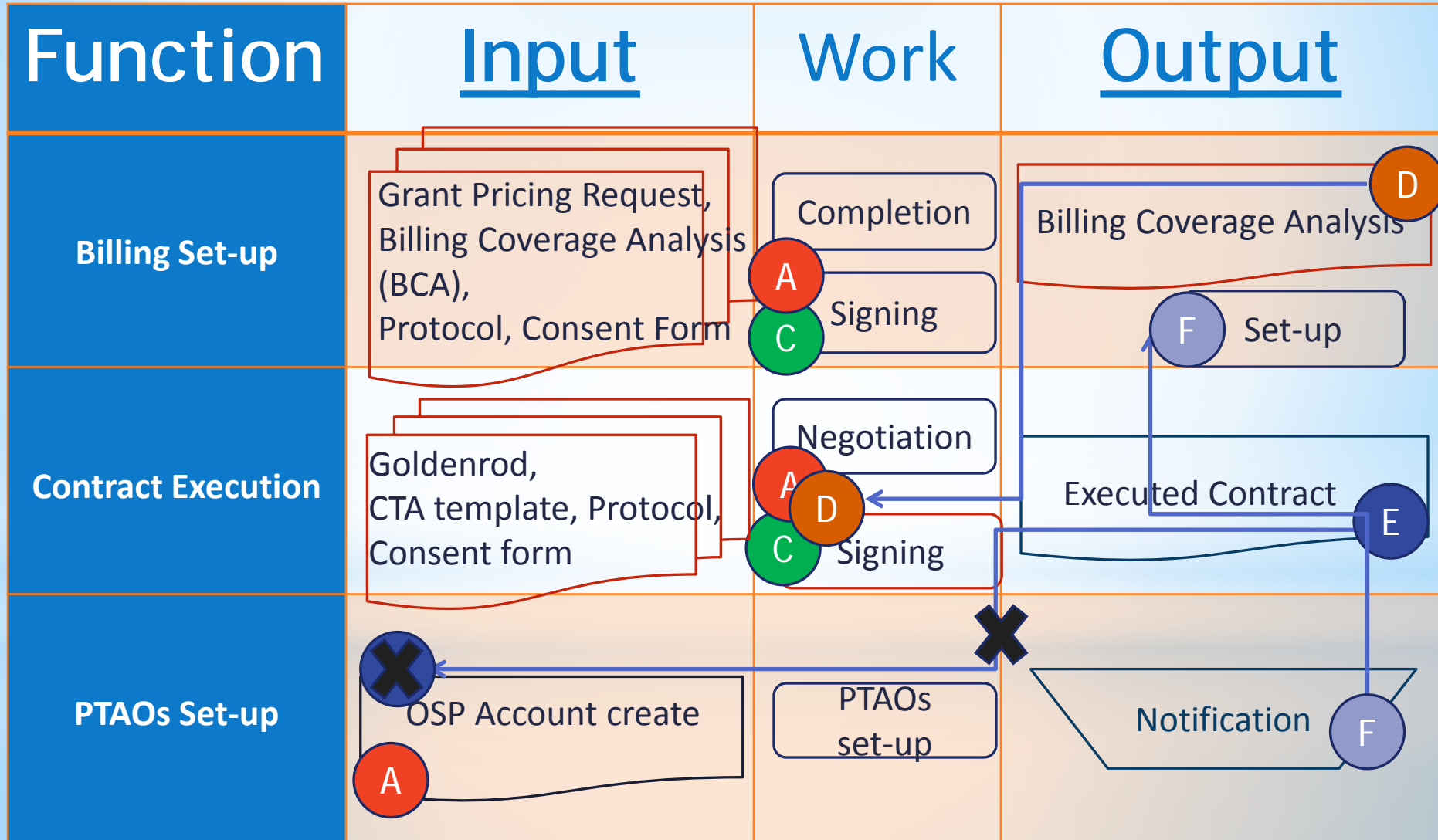
# Expanding value stream analysis



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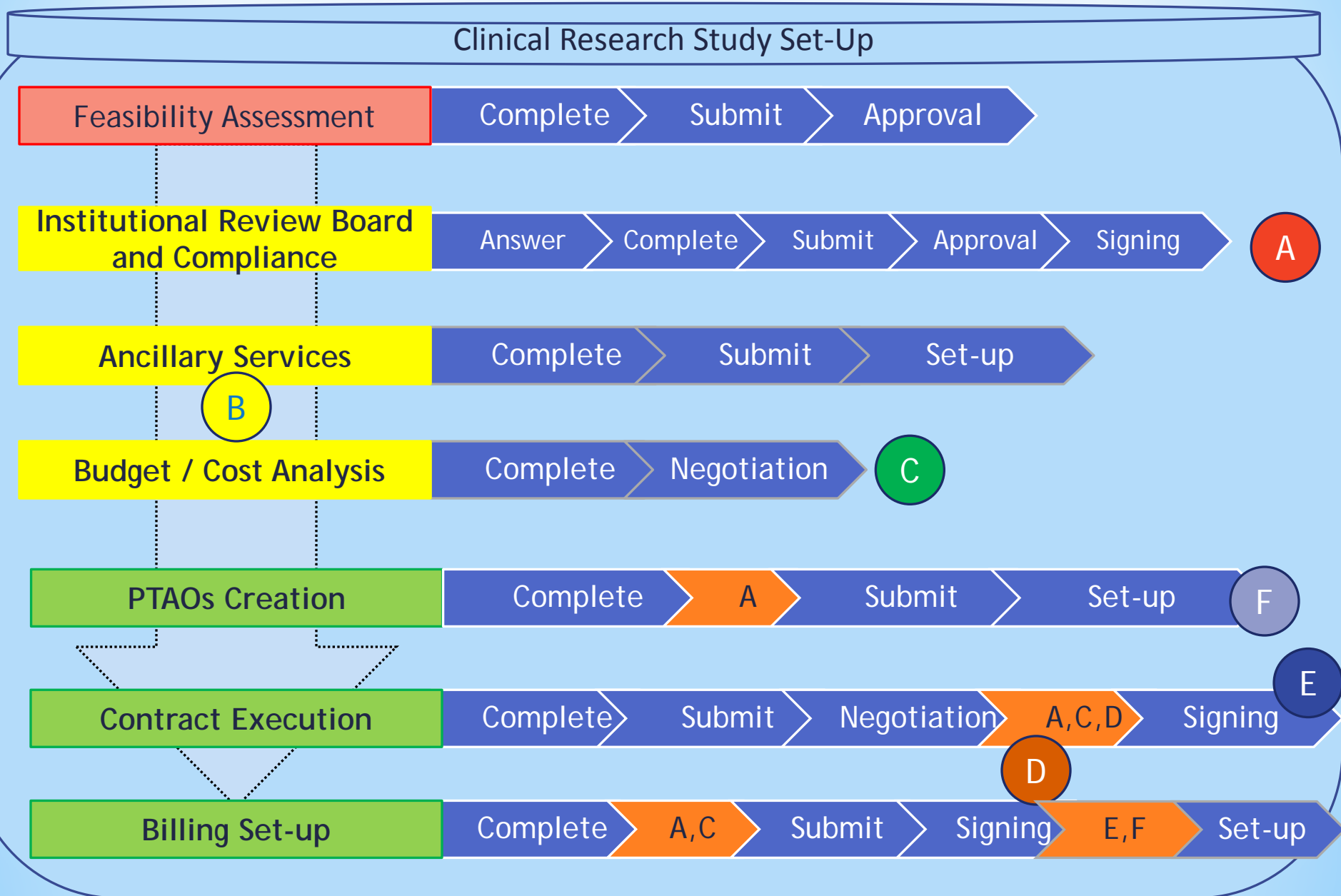


# Expanding value stream analysis

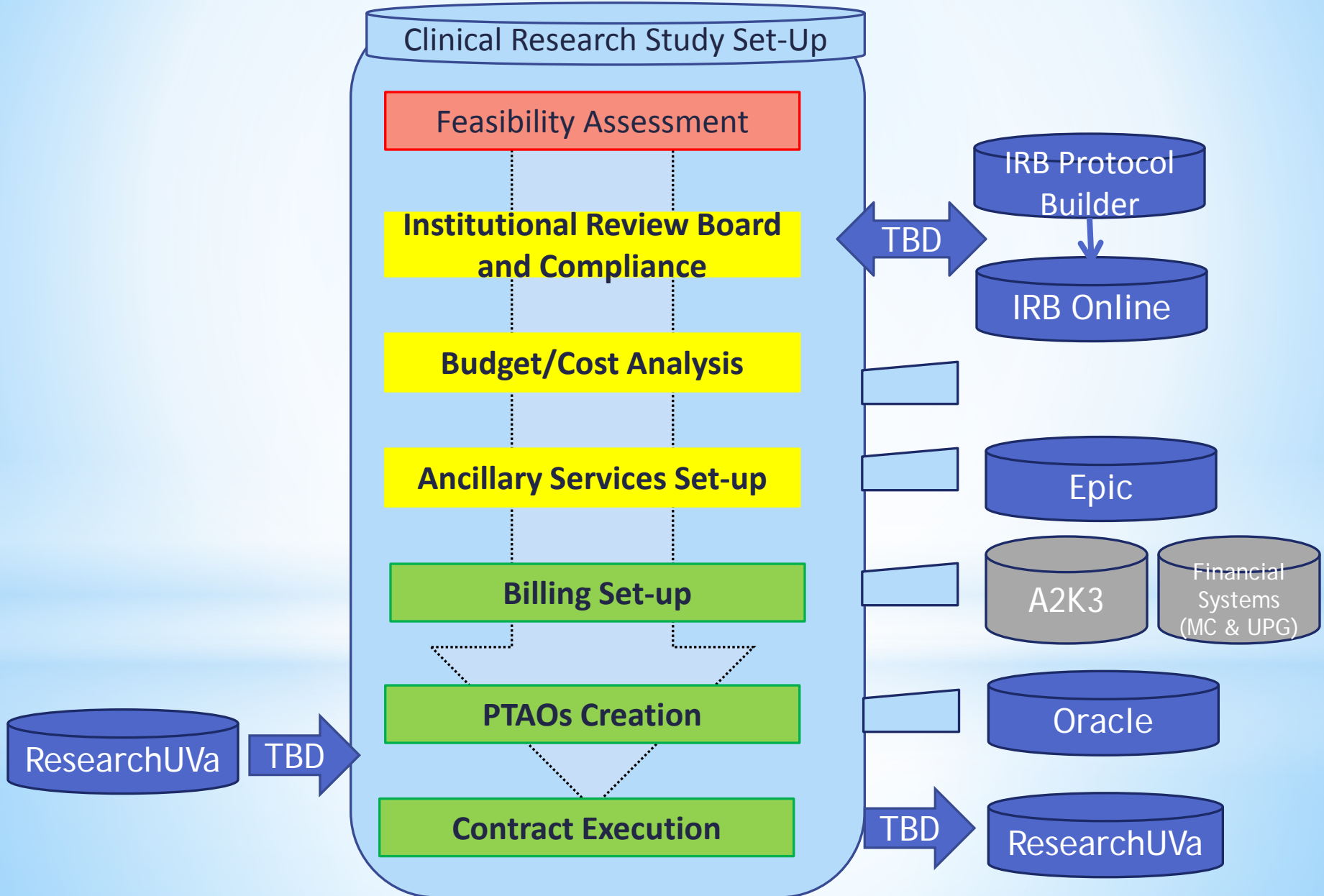




# Concept of target condition



# Opportunities for integration



# Framework for analysis and specification

Listing questions from each form

Indicating the required forms

Analyzing:

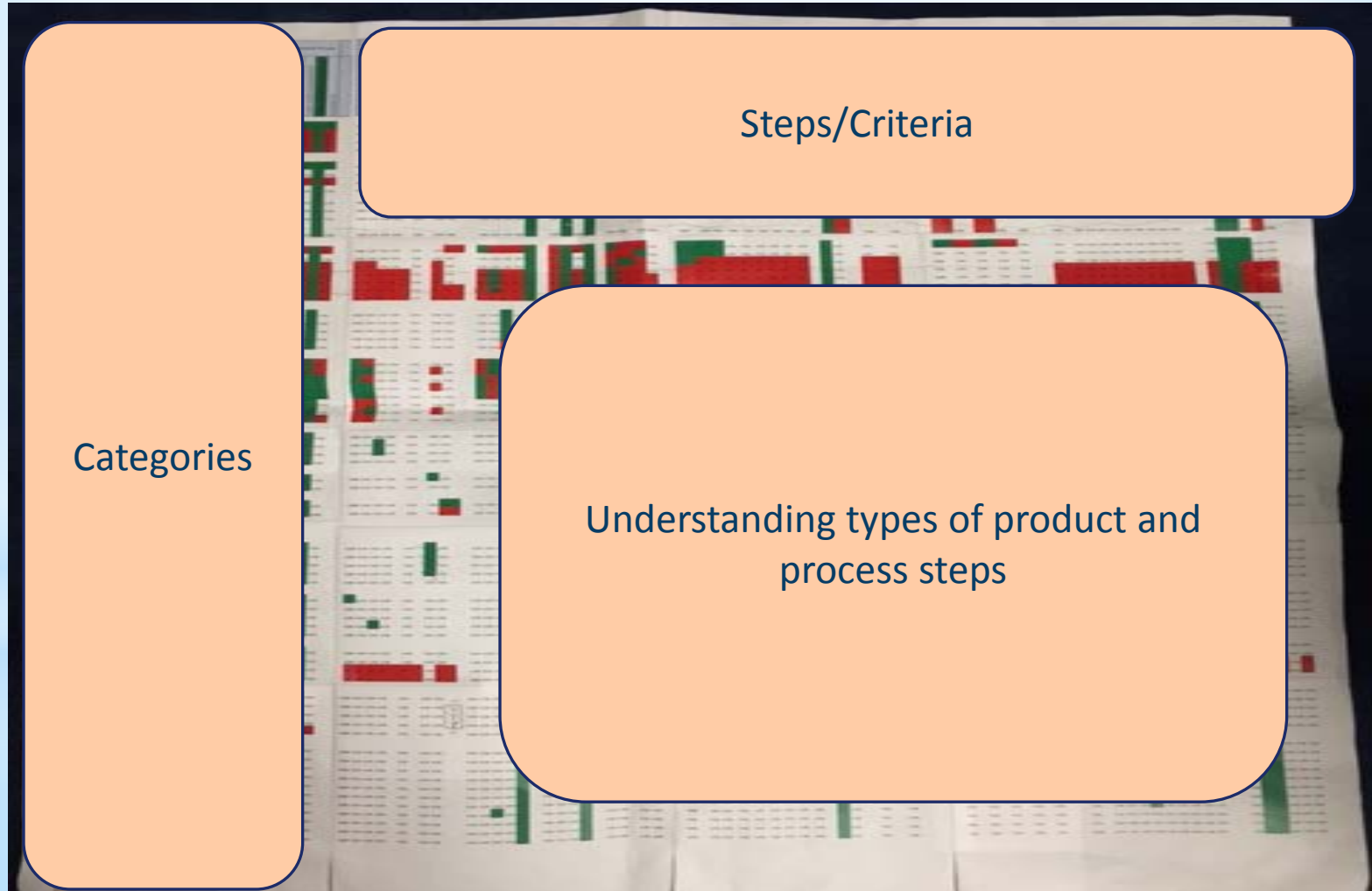
- Purpose
- Duplication?

Specifying:

- Definitions
- Constraints
- Validations
- Ability to prepopulate

225	Will a potential subject who is a prisoner be allowed to enroll in this study?	Subjects
226	Will you enroll a woman if she is pregnant?	Subjects
227	If a woman is pregnant or becomes pregnant while in this study would the study pose a risk to a fetus?	Subjects
228	Would participation in this study pose risks to a fetus if a male subject were to father a child?	Study
229	Will this protocol involve fetuses or human in vitro fertilization?	Study
230	Will cognitively impaired subjects be allowed to enroll in this study?	Subjects
231	Will the study require surrogate consent?	Consent
232	Do you expect to enroll subjects who will not be able to read or speak English?	Subjects
233	Do you plan to translate the full consent into the other language?	Consent
234	Is Spanish the language of the non-English speaking subjects?	Subjects
235	Will the subjects receive compensation or reimbursement for expenses for participating in this study?	Subjects
236	Will this study enroll ONLY healthy subjects?	Subjects

# Process: framework for steps and product analysis



# Feasibility Assessment

*Should we do it? Can we do it? How do we do it?*

Goals: creating standard and systematic approach to initiating a clinical research study and conducting feasibility assessment

Value to Principal Investigator and Division/Department

- Awareness and education
- Preparation and integration
- Planning, prioritization, and commitment

Process

- Principal Investigator/Study team -> Departmental Committee
- Start: draft protocol or sponsor protocol
- Categories: general information, science, patients needs and availability, enrollment considerations, cost estimation, sponsor considerations, committee review, decision and priority

# Survey

*(Results have been shared with the advisory team)*

## Goals:

- Baseline metrics for overall satisfaction, timeline, and meeting recruitment goals
- Priorities within our value stream
- Satisfaction related to: education and awareness of the process, ability to submit requests, and supporting systems
- Current practices related to: feasibility assessment and data tools development to conduct a study
- Ideas for improvement

## Process:

- Survey invitation sent to SOM, Interns/Residents with active IRB Protocols. Follow up with Department/Center administrators.
- Sent on April 29, closed on May 12, 2015
- **Current step: analyzing open-ended questions**

Thanks to Wendy Novicoff, Public Health Sciences for guidance, help, and learning experience!

# Next steps – next 6 weeks:

## Target condition

- Process dependency and integration
- Systems integration
- Enhance specification and decision to automate
- Data specification (starting with IRB, prioritizing and adding additional forms)
- Product and related steps

## Feasibility assessment

- Testing the concept, adjusting the specification

## Survey open-ended analysis

## Creating baseline, setting success metrics

# Next steps, stay connected

## Next meeting:

- An invitation will be sent for August 6, Thursday

## Stay connected:

- Let us know if you want to be more involved
- Check project website: <http://cr.med.virginia.edu>



The screenshot displays the website for the University of Virginia School of Medicine, specifically the page for "Clinical Research Improvement in Systems and Processes". The header includes the university name, a search bar, and navigation links for Education, Research, Departments, and Community. The main navigation menu contains links for Home, Project Events, Institutional Alignment, Project Team Members, Contact Us, and Updates and News. The "Upcoming Events" section features a "Project Update 1" event scheduled for Friday, May 8, 2015, from 2:30 PM to 3:30 PM at Jordan Hall, G1&G2 (ground floor). Below the event details is a "U.Va. Clinical Research News" section and a large image of the Rotunda building.



# Thanks to the best workgroup ever

- \* **Cricket Birk, RN CCRN**  
Clinical Research Coordinator, Department of Anesthesiology
- \* **Sandra Burks, RN, BSN, CCRC**  
Associate Director, Surgical Therapeutic Advancement Center
- \* **Stewart P. Craig, MS**  
Assistant Dean for Research Administration  
Director, Office of Grants and Contracts
- \* **Lori Elder, RN BSN CCRA**  
Director, SOM Clinical Trials Office
- \* **Susie Hoffman, RN BSN CIP**  
Director: IRB for Health Sciences Research
- \* **Lynn Koplín, M.A., CRCP**  
Assistant Director of Contracts, Office of Sponsored Programs
- \* **Johanna Loomba, BS, CCRC**  
Director, UVa Neurosurgery Clinical Research
- \* **Goga Radakovic, MD, CCRC**  
Director, Office of Clinical Research, Cancer Center
- \* **Catherine A. Reniere, MA**  
Cancer Informatics Program Manager

# Thank you all!

