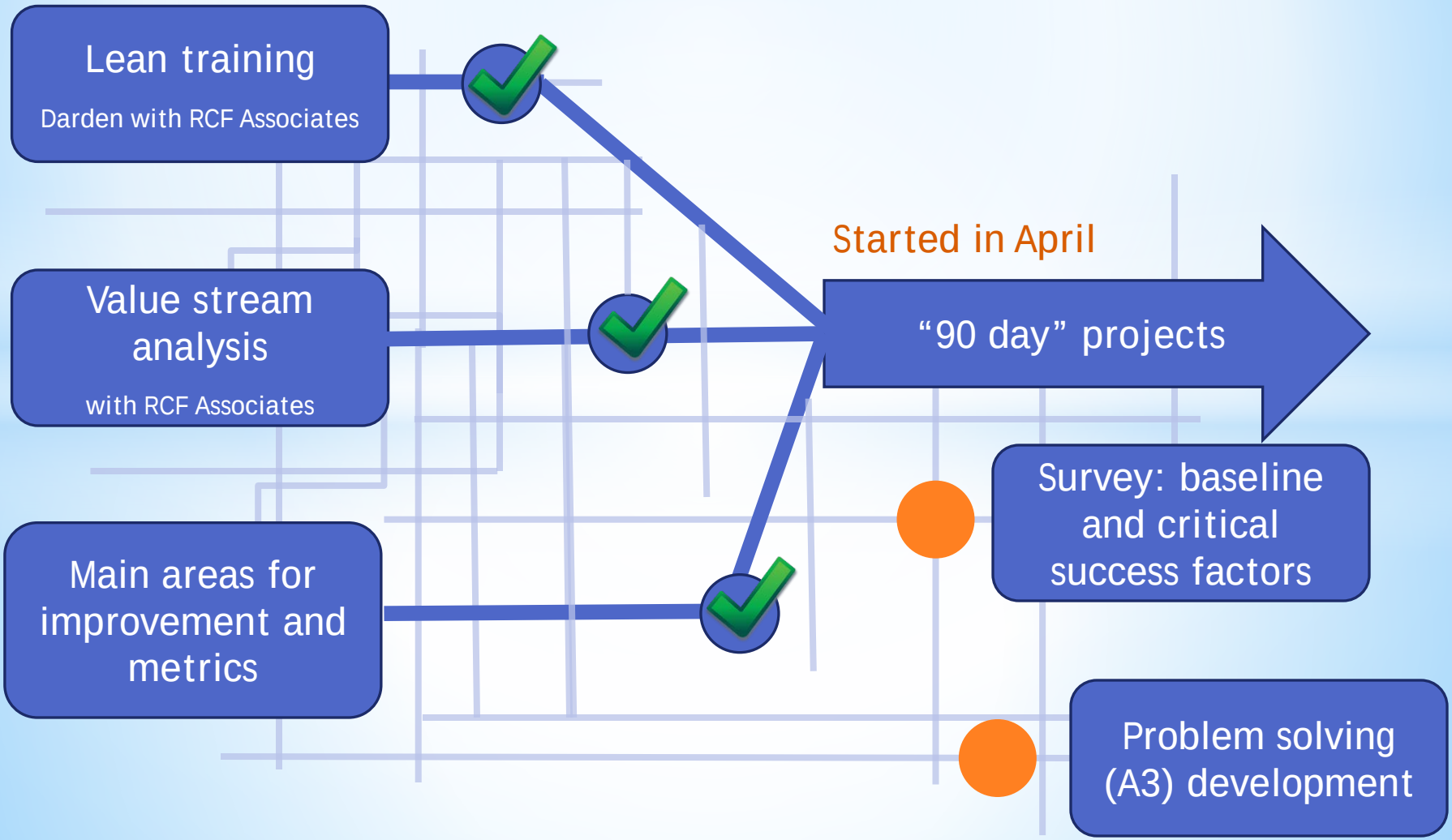
Clinical Research Improvement in Systems and Processes

May 08, 2015

The map of our journey



Lean training at Darden: concepts

* **Three types of work:**
  * Value adding
  * Waste
  * Non-value adding but necessary
* **Wastes: TIM WOOD + U + C**
  * Transport
  * Inventory
  * Motion
  * Wait
  * Overproduction
  * Over-processing
  * Defect
  * Un-engaged, underutilized talent
  * Confusion
  * Harm
* **Flow, Pull**

Training by: Elliott Weiss, Professor of Business Administration at Darden School of Business and RCF Associates, Austin English

Lean exercise: building with Lego

For the purpose of this presentation,
let's assume the assignment was really challenging and
we were building…Taj Mahal

Our original set-up

Our challenge: achieving flow

Our learning experience.. and fun

"Need to ask more questions and ask ourselves "why"…"

"Validate quality as we go"

"Importance of communication"

"Let's not do *unproductive* things *efficiently*, eliminate waste first"

"Let's not underestimate the value of improving little things"

"Can do anything we want to do", "Importance of creativity"

"Wow, change was tough"

Value stream definition and clinical research product

Value stream is a sequence of actions required to develop a product. Value stream analysis focuses on the flow of information or material necessary to generate the product.

Our product is an “Approved Research Protocol”

Project scope

Scientific Investigation

Start: Protocol design or sponsor protocol

- **Institutional Review Board & compliance**
- **Budgeting**
- **Billing**
- **Ancillary services**
- **Contract execution**

Study Start-Up

Study Conduct

- Patients Enrollment, Location
- Clinical Trial Billing
- EPIC
- Good Clinical Practice/ICH
- Maintain the IDE
- Maintain the IND
- Time & Effort Reporting

- Close IND or IDE
- Close with clinicaltrials.gov
- Close with IRB-HSR
- Leaving UVa (if applicable)
- Records Management/Retention

Study Close-Out

End: The study is ready to enroll patients

Clinical Research

Clinical Research Study Results

Clinical research study start-up

Assumptions: the funding is secured, although a final budget may not yet be established.

Start: The investigator has a protocol design or a sponsor protocol

End: The study is ready to enroll patients

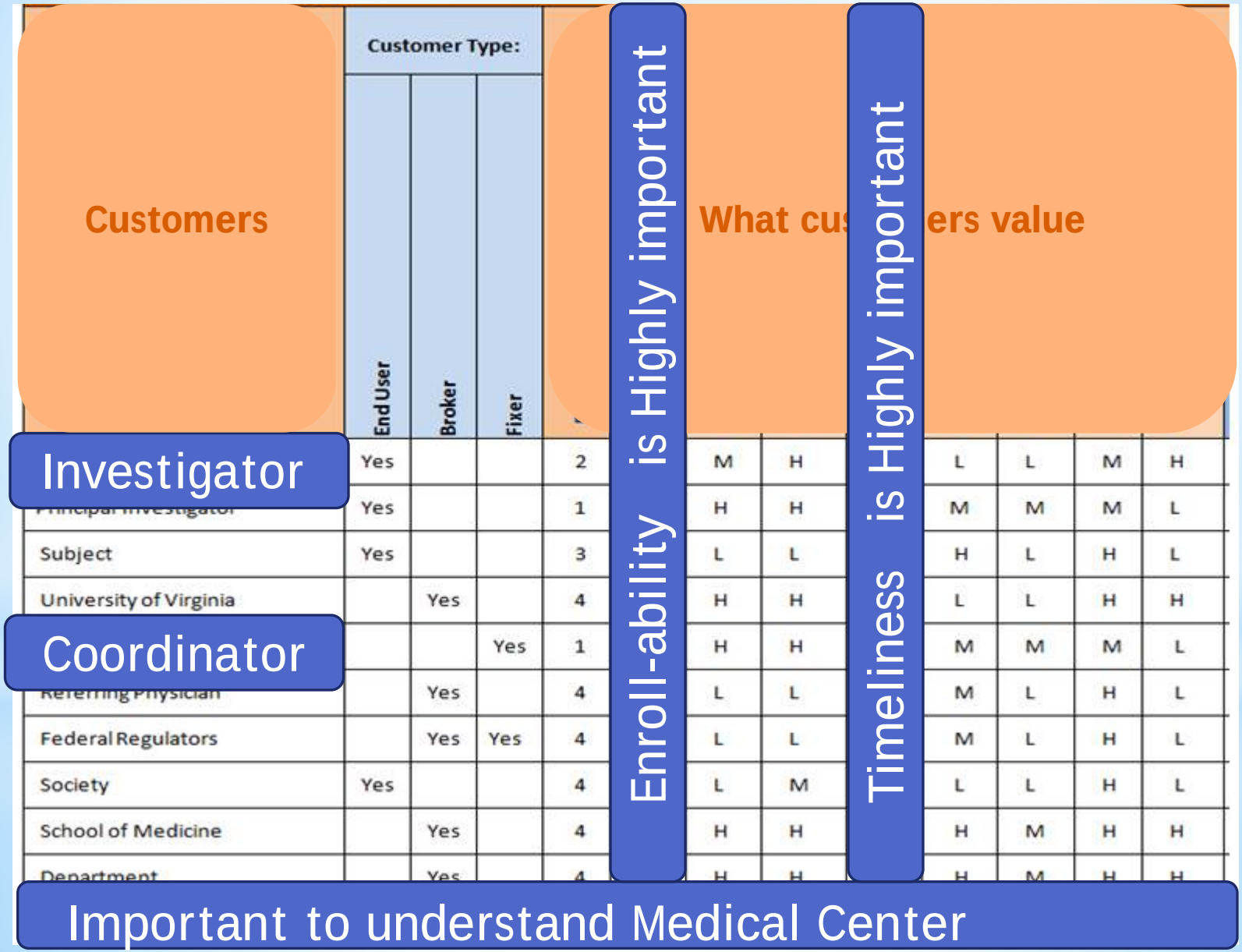
Types of studies:

* Industry initiated
* Investigator initiated
* Cooperative Group
* Federally, NIH funded
* Private foundation initiated

Who are our customers?

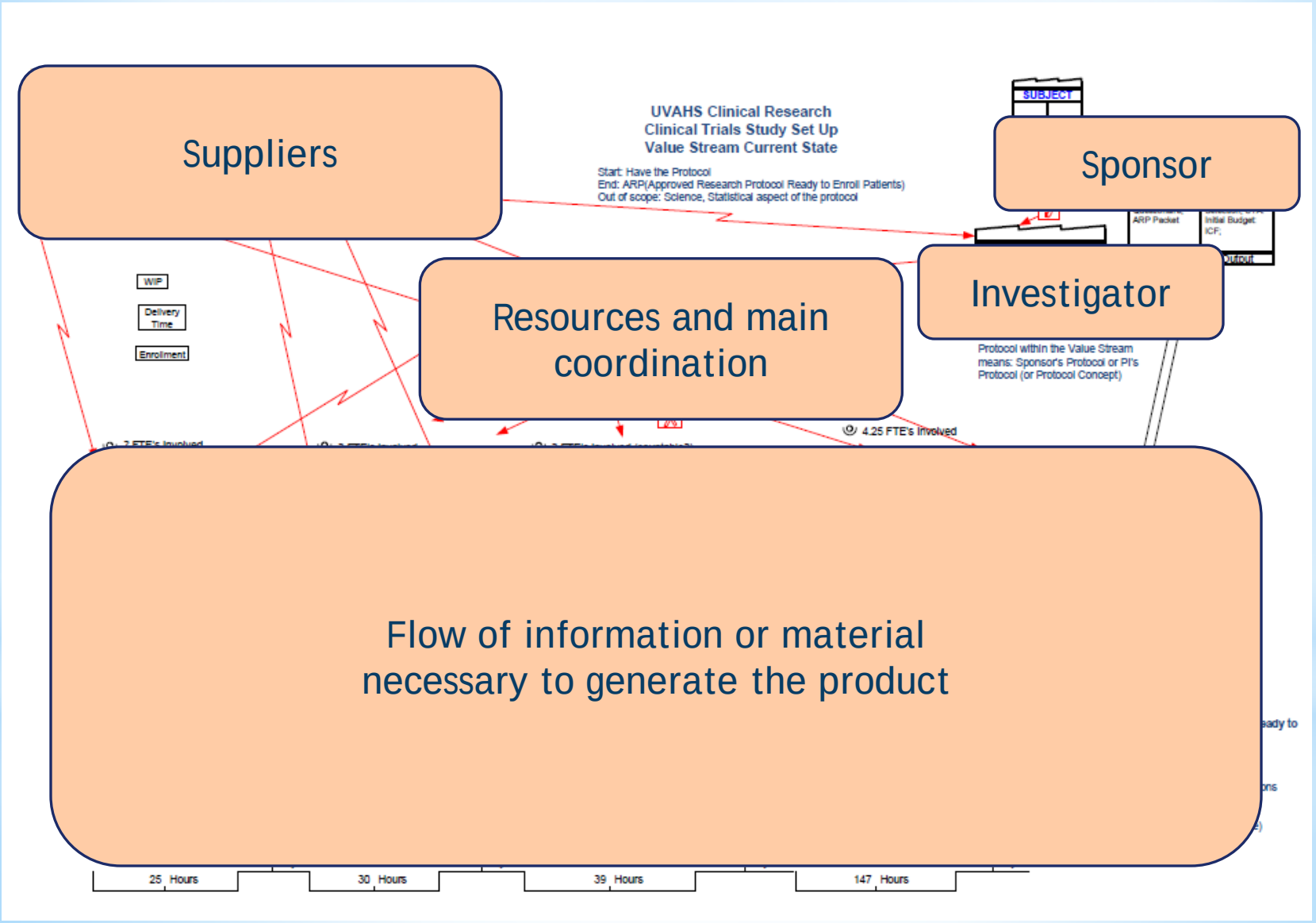
* Subjects (patients)
* Society
* Principal Investigators
* Clinical Research Coordinators
* Departments
* School of Medicine
* Medical Center
* University of Virginia
* Referring Physicians
* Federal Regulators
* Sponsors (including Contract Research Organizations – CROs)

Understanding of our customers



Customers	End User	Broker	Fixer								
Investigator	Yes			2	M	H		L	L	M	H
[illegible]	Yes			1	H	H		M	M	M	L
Subject	Yes			3	L	L		H	L	H	L
University of Virginia		Yes		4	H	H		L	L	H	H
Coordinator			Yes	1	H	H		M	M	M	L
[illegible] Physician		Yes		4	L	L		M	L	H	L
Federal Regulators		Yes	Yes	4	L	L		M	L	H	L
Society	Yes			4	L	M		L	L	H	L
School of Medicine		Yes		4	H	H		H	M	H	H
Department		Yes		4	H	H		H	M	H	H

Value stream map



Generating our product (simplified ☺)

Protocol

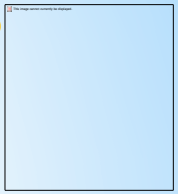
Institutional Review Board (including review/approval by compliance committees) → IRB Approved Protocol and Consent Form

Budget preparation and negotiation → Negotiated budget

Ancillary services set-up → Technical instructions (and Epic Order set)

Billing (Medical Center and University Physicians Group) set-up → Billing set-up

Contract negotiation and execution → Executed Clinical Trial Agreement (and PTAOs set-up)

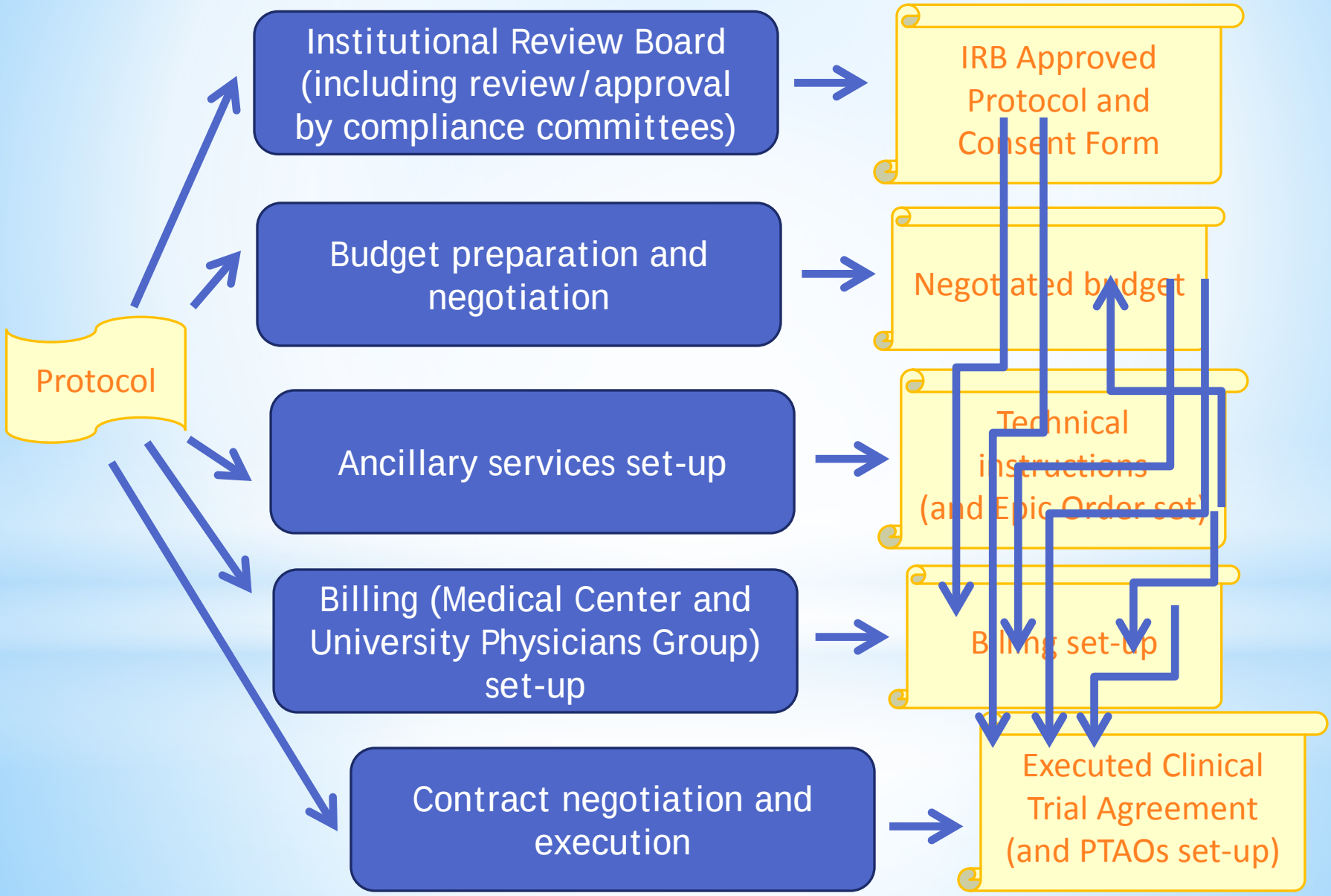


Missing anything?

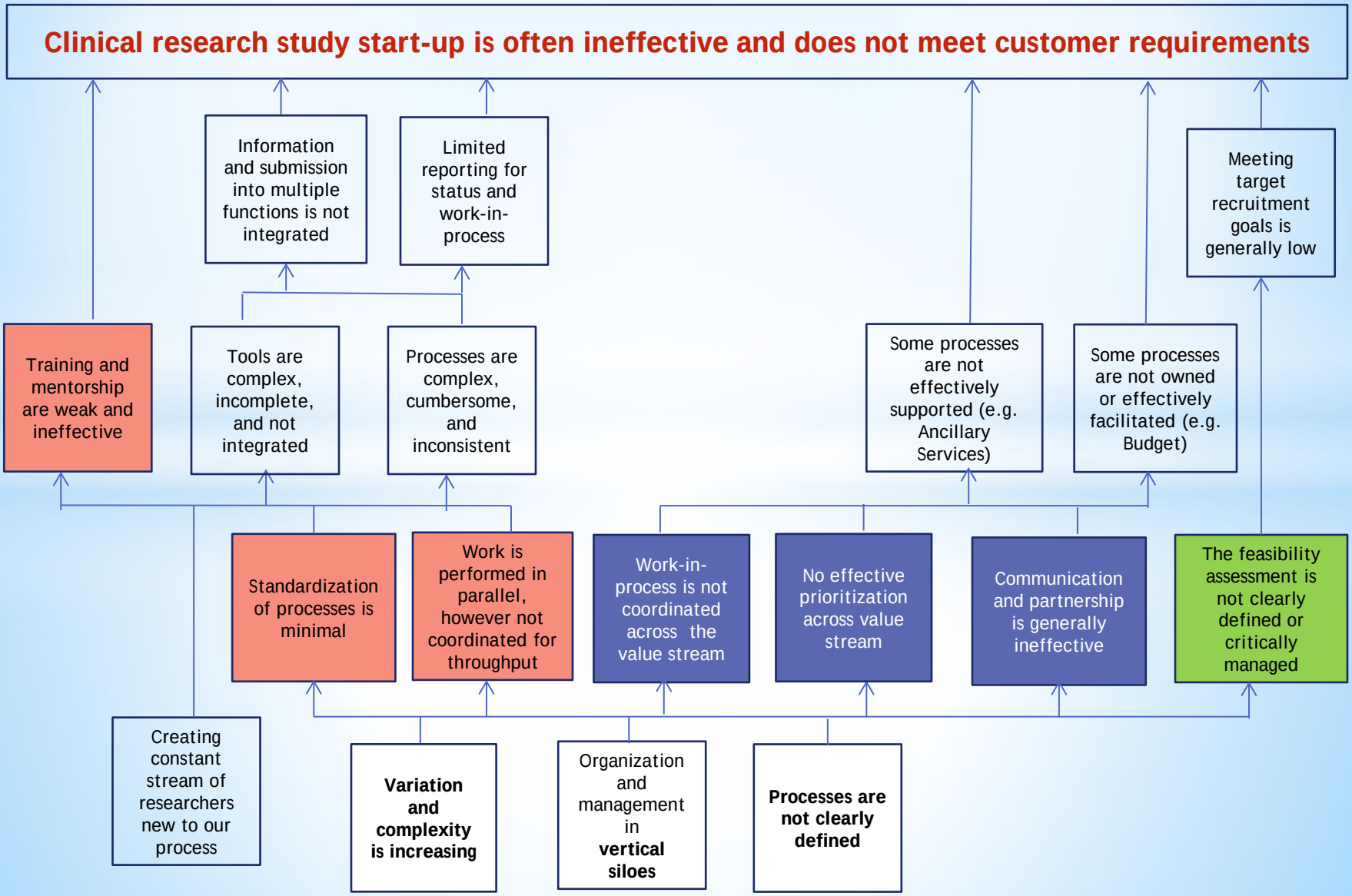
We perform complex work in siloes.

We perform most of work in parallel, however not effectively coordinating for the final product.
We are lacking effective stewardship of a value stream.

Generating our product (more realistic, still simplified)



Our story - root cause analysis



A3s – approach, sneak peek

* Identify the problem, analyze current state, find the root cause, identify a future state, and implement a plan.
* **Main areas for improvement - our A3s:**
  * Process and Education

    Our current processes, systems, as well as lack of comprehensive training make it extremely challenging to start up a clinical research study in a timely manner. We are not positioned for success.

  * Feasibility Assessment

    There is no efficient, integrated, or standard process to determining the feasibility of conducting clinical research studies. Clinical research studies are activated with little possibility of meeting fiscal or study goals.

  * Stewardship of a value stream

    There is limited recognition of a “value stream”, (i.e. all essential components required to manage and strengthen clinical research at UVa) and it negatively impacts UVa’s ability to support the strategic direction and daily operations.

Three important metrics

1. Manage work-in-process
2. Reduce turnaround time
3. Increase satisfaction

Managing work-in-process

will lead to on-time delivery,

which in turn will lead to higher enrollment rate and

ultimately increased satisfaction.

Survey

* **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
* Survey invitation sent to **SOM, Interns/Residents with active IRB Protocols.**
* **Survey sent on April 29, will close on May 12 EOD**
* **Thanks to Wendy Novicoff** for endless guidance, support, and learning experience!

Next steps, stay connected

* **Next meeting in 6 weeks:**
  * An invitation will be sent for June 19, Friday.
  * The update will include survey results and A3 development.
* **Stay connected:**
  * If you have received the survey - complete the survey!
  * Let us know if you want to be more involved
  * Check project website: http://cr.med.virginia.edu

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 Koplin**, 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!