

Industry-Sponsored Clinical Trials Improvement Efforts

Update

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Summary of Improvement Workshops

Problem Statement: It is essential to decrease the time it takes UCSF investigators to initiate industry-sponsored clinical trials, as well as to improve our clinical research operations in general.

Goals/Desired Outcomes: Improve the process to activate an industry-sponsored clinical trial. Improve UCSF's efficiency and reputation as a place to do industry-sponsored clinical trials.

Some Key Areas to Address Initially:

- Provide good data to better track and report on the status and length of time to clinical trial activation;
- Ensure adequate staffing of the central offices that support the clinical trial activation process;
- Increase IRB panel member recruitment;
- Develop study intake and triage functions; and
- Establish a troubleshooting team.

Executive Summary

Key Results:

validating **baseline data** on how long key components of the process take

integrating systems to better track the progress of clinical trial activation

filling vacant positions

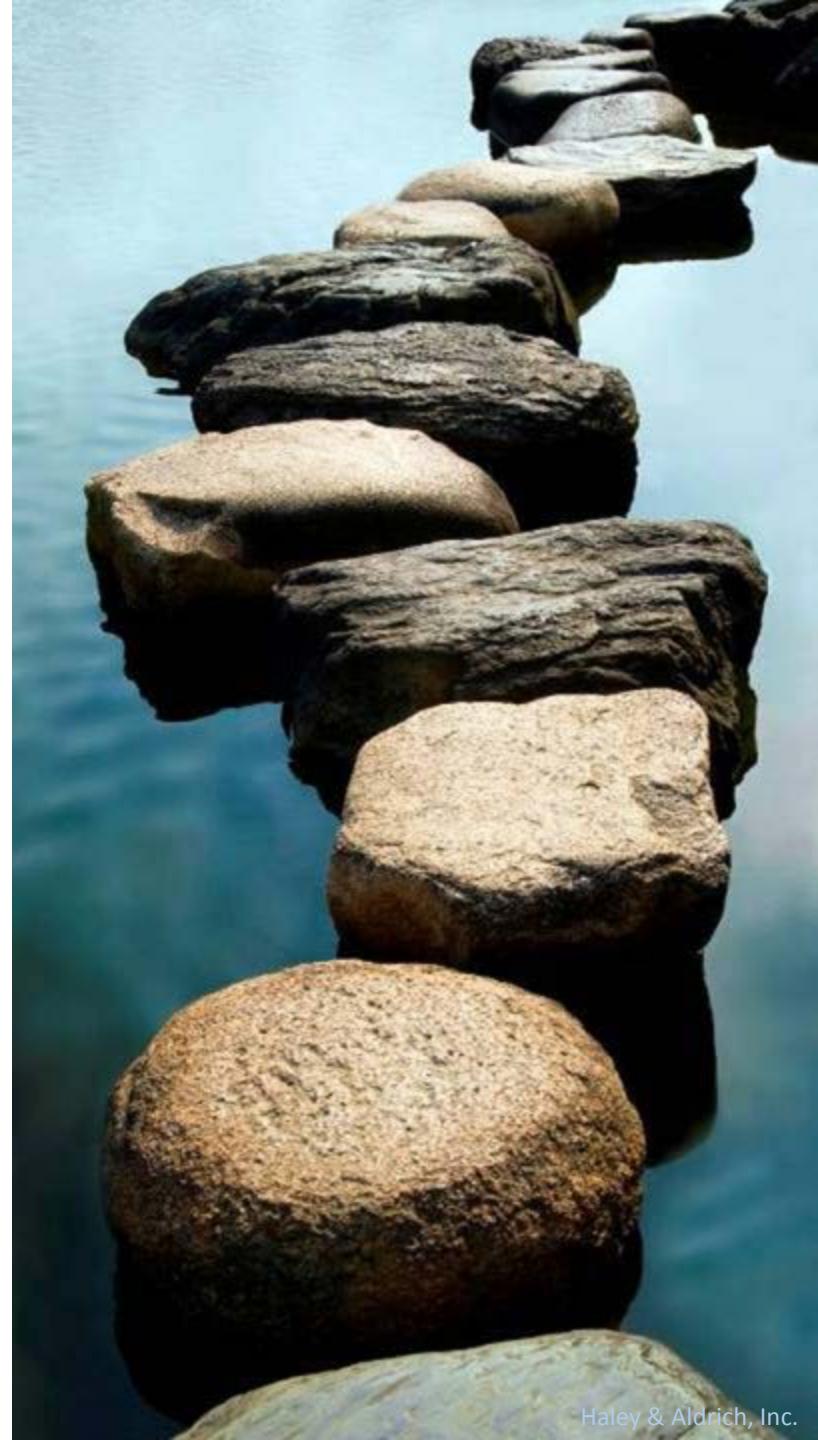
increasing IRB panel member recruitment

developing new org roles for study intake and triage

as well as establishing a **concierge program and/or troubleshooting team.**

Topics covered

- Lean Learning
- Customers and Value Assessment
- Current State Mapping
- Problem Identification
- Target Goal Identification
- Idea Generation
- Future State Mapping
- Gap Assessment and Prioritization of Countermeasures
- Action Plan Development
- Celebration



Workshop Participants

Hal Collard
Lindsey Criswell
Thomas Cunningham
Lidia Espino
Laurie Herraiz
Kent Iwamiya
Jim Kiriakis
Annie Luetkemeyer
Kate Nolan
Cat Savangsay
Peter Sayre
Brian Smith
Eunice Stephens
Winona Ward

Goal

Improve UCSF's efficiency and reputation as a place to do industry-sponsored clinical trials

The process will be:

- A positive experience for all involved
- Clear and transparent, with
 - defined roles & responsibilities (RACI)
 - standard operating procedures (SOPs) that accommodate both complicated and simple cases
- Fast **enough** to participate in the trial (be a player)
- Accurate **enough** to meet requirements
- Data-driven
- Compliant (to keep UCSF Health at the table)

Customer Value Assessment

The team identified key customer groups and assessed what they value. Customers and values were grouped into similar categories and values that encompassed all groups were placed at the top of the chart. The team selected the values they thought were the most important values to the main customers.



Main Customers

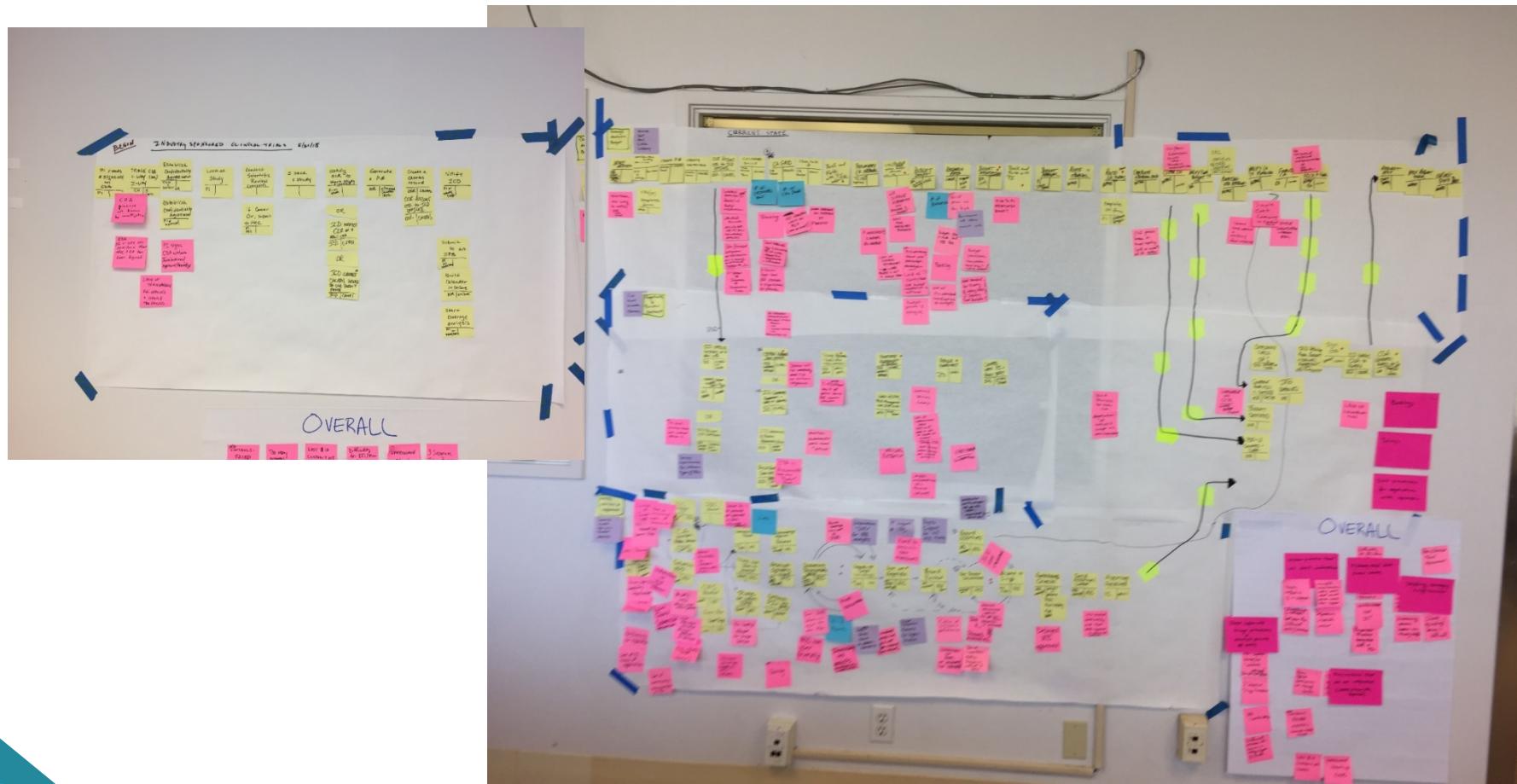
1. Investigators
 2. Institution (UCSF)
 3. Sponsors

Top Values

1. Fast enough to participate
 2. High Quality
 3. Accurate
 4. Value for Cost

Current State Value Stream Mapping

This Lean tool helped the team visually represent what actually happens ("WAH") in the current process. The group identified sources of waste and problems and reviewed the entire process to ensure that the steps were accurate and understood by all members.



Problem Themes

The problems of the current state system were grouped into six key themes:

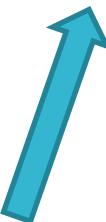
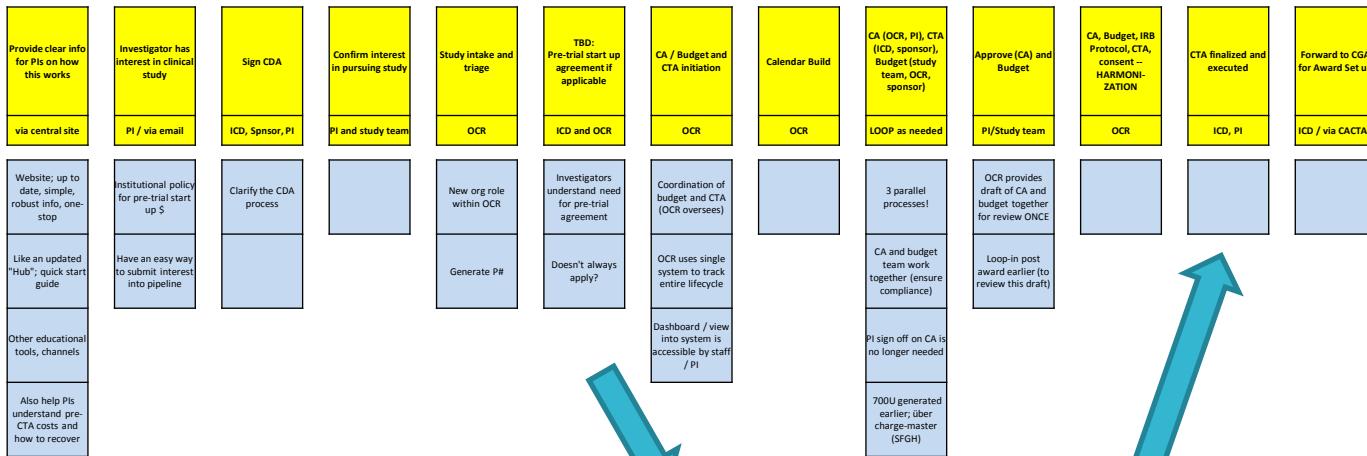
1. Many systems are not integrated (CACTAS, OnCore, iRIS, PeopleSoft)
2. Unclear process that all don't understand
3. Multiple points of entry to the process and three separate triage processes
4. Siloed processes between budget and contract negotiation with the sponsor
5. PI/Study staff do not know the status of their trial
6. Staffing shortages and high turnover add to delays and backlogs

Future State Map

Industry-Sponsored Clinical Trials: Future State Map produced during Flow Kaizen June 2018

Version: July 2, 2018

Yellow are process steps; Light blue are underlying assumptions about conditions that are in place (which may require getting in place)



OVERALL ASSUMPTIONS APPLICABLE to ALL STEPS

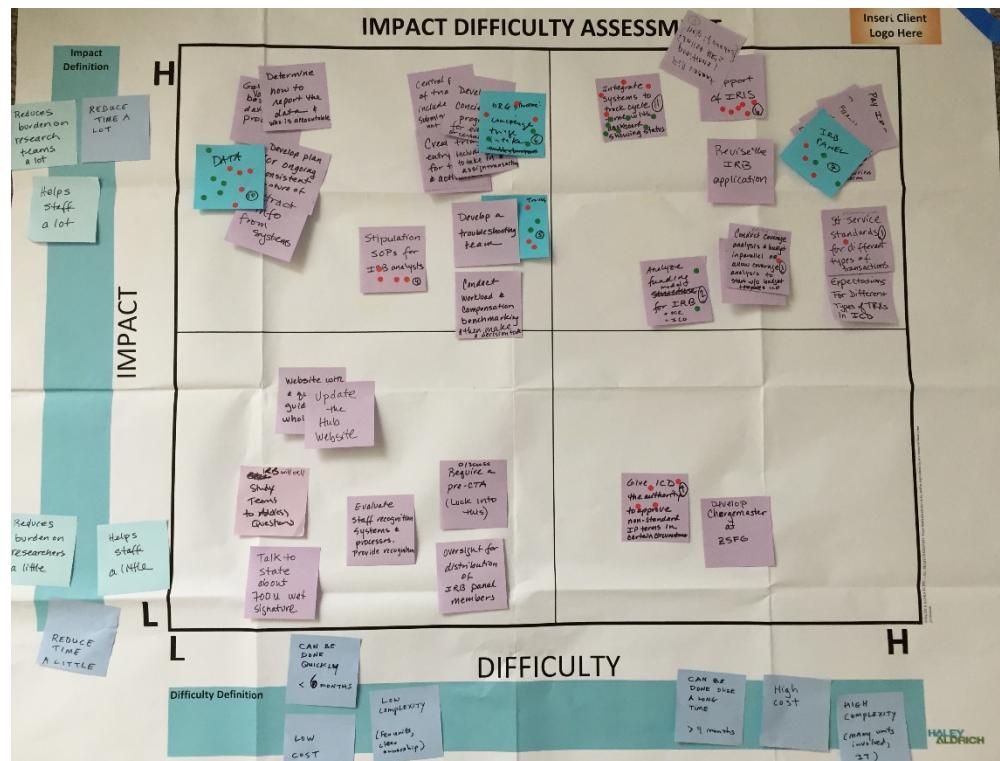
Each study has an Ops Analyst / PM ("Concierge")	New trouble shooting unit exists to track "stuck" items and address problems	SOPs are established for operational steps
Capture / analyze data (via reports) for better decision making and adjustments	Maintain understanding of regs, guidance, UCOP input, etc	Built-in processes for continuous improvement / PDCA

Follow the IRB process OCR, PI, HRPP / iRIS etc	IRB approval IRB / iRIS	IRB notifies OCR IRB / via email from iRIS
Career dev opps + incentives for panelists Larger, more flexible IRB (esp faculty) How to: submit clean application Retrain IRB staff and panel members Revise / update iRIS application Std times set for processing	PI contacted PRIOR to board review Expanded iRIS support	

(See Excel document for more details)

Gap Assessment and Prioritization of Countermeasures

After the future state map was complete, a gap assessment was conducted comparing the current state and the future state. The team identified areas that need development in order to implement the future state



Using an impact/difficulty chart, ideas were prioritized based on a high to low impact on the top customer values and the team's definition of high to low difficulty to implement

Quick Win Process Improvements

During the month of June 2018, OCR made the following improvements which will be implemented once all OCR staff are trained in the Fall.

- No more PI Signoff
 - The PI approval of Coverage Analysis step has been removed from the workflow
 - This step averages roughly 18 calendar days (N=50 sample)
- 700U's Generated Earlier
 - Used to be generated when budget finalized between study team and OCR
 - Now will be generated when study is ready for calendar build, which allows for any positive disclosures to be worked on (COI Committee) in parallel with OCR processes
- P Numbers Generated Earlier
 - CC needs P# for IRB application, OCR will now proactively provide the P number to the Cancer Center PPM to allow for quicker IRB application submission
- CACTAS Records Generated Earlier for Oncology Studies
 - Used to be created after eProposal packet was put together and budget was finalized
 - Now the OCR will initiate the CACTAS creation when the OCR is notified of a calendar build request
- Create templates for budget elements (in process)

Action Plan

A list of action items was created to help implement the priority improvements identified by the team. An owner (s) was identified for each action item. Next steps will be to confirm the owners, determine resources needed as well as timing.

	Action Item	Owner	Resources Needed	Timing
1	Validate baseline data (time) for the process; develop plan for ongoing consistent capture of data; determine how to report the data and who is accountable	Winona, Eunice, Jim, Laurie	CGA data analyst Lei Zheng	TBD
2	Integrate systems to track cycle time with dashboard showing status	Winona, Eunice, Jim, Laurie	IT rep \$	TBD
3	Determine best way to increase recruitment for IRB Panels: Pay IRB members or provide non monetary incentives; Research RVUs/qRVUs; faculty service on IRB needs to be part of career progression; have more IRB members	Laurie/Peter	TBD	TBD
4	Fill vacant positions in OCR, IRB, and Industry Contracts with HR's assistance	Head of each unit – Eunice, Jim, Laurie	TBD	TBD
5	Determine new org role/create one entry point – triage/intake team, concierge and/or troubleshooting team	TBD	TBD	TBD
6	Obtain IT support for iRIS	Brian, Laurie	TBD	TBD
7	Create stipulation SOPs for IRB Analysts	Kate, Laurie	TBD	TBD
8	Give ICD the authority to approve non-standard IP terms in certain circumstances	Jim	TBD	TBD

Other Improvement Ideas Identified

Low Impact / Low Difficulty (Possible)

1. IRB call study team to address questions
2. Update the hub website (include quick guide for whole process)
3. Evaluate staff recognition systems and processes (improve recognition)
4. Talk to state about need for 700u wet signature
5. Look into requiring a pre-CTA
6. Oversight for distribution of IRB panel members

High Impact / Low Difficulty (Implement)

1. Conduct workload and compensation benchmarking and then act on the results of the benchmarking study

High Impact / High Difficulty (Challenge)

1. Revise the IRB application
2. Analyze funding model for IRB, OCR, and ICD
3. Conduct coverage analysis and budget in parallel
4. Create career development pathways for staff. Address barriers to retention.
5. Set and communicate service standards for different types of transactions in ICD

Low Impact / High Difficulty (Kibosh)

1. Develop enhanced charge master at ZSFG

Ideas to Improve Relations with Industry Sponsors

- Once the process has been improved, re-brand/re-introduce UCSF to industry sponsors
- Create a landing page for industry sponsors which explains how they can engage UCSF for clinical trial agreements. Page provide stats and specific info on UCSF targeted to industry (time, enrollment successes)
- University-level networking to ‘advertise’ key opinion leaders to industry

Next Steps

- Determine resources needed
- Newly-formed “Industry-Sponsored Clinical Trials Process Improvement Task Force” will pick up where the workshops left off and shepherd the process of ongoing improvement over the coming year:
 - Shepherd the implementation of the desired future state process map.
 - Track the progress of the list of action items identified during the process improvement workshops.
 - Continue to assess other process improvement ideas.
 - Communicate the status of these improvement efforts.
- PMO to continue to assist these efforts

Questions or Comments?



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