SPECTRUM HEALTH

A Journey Through Research Administration Process Improvement

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The Basics

No conflict of interest to report

Our Journey Today

- Background and perspective
- Adopting Kaizen Culture for process improvement (PI)
- Describe the launch or our tool called ‘RiHub’
- Deeper dive into the tools of continuous improvement
- Group PI activity – tennis ball challenge
- Back to RiHub – example projects and lessons learned

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Variability in Research Administration Environment

- No two research departments are the same
- High variability across the administrative field
  - Types of studies
    - Different funding sources (ie. NIH vs. philanthropic vs. industry)
    - Different study structure (ie. interventional/observational, expanded access)
  - Types or organizational structures/staffing models
  - Levels of acceptable risk
  - Maturity of Research Program(s)

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Commonality in Research Administration Environment

What can be considered common?

- Regulatory requirements
- Financial management strategies
- Team management strategies (HR tactics)

And.....

CONTINUAL IMPROVEMENT

Nature of perpetual process changes

Generally speaking.....

In today's world, processes change frequently by nature

- New tools being introduced (IT, Office, Clinical)
- Rules and policies changing (Federal regulations, system policies)
- People change (Vision/mission/leadership styles)

The journey to improve those processes is something we all share in common, and is (hopefully) never ending.

My Perspective

- My Background
- Current lens I am looking through – Non-academic, not for profit hospital system - Spectrum Health
  - Health system comprised of 14 hospitals in Western Michigan, 31,000 employees, 4,200 Physicians/APP's
  - Office of Research (SHOR)
    - *100 staff across 4 areas including Research Oversight (IRB), Sponsored Programs, Research Finance, and Clinical Operations Teams.*
    - *Managing approximately 1,000 studies that include industry sponsored trials, registries and investigator initiated research.*

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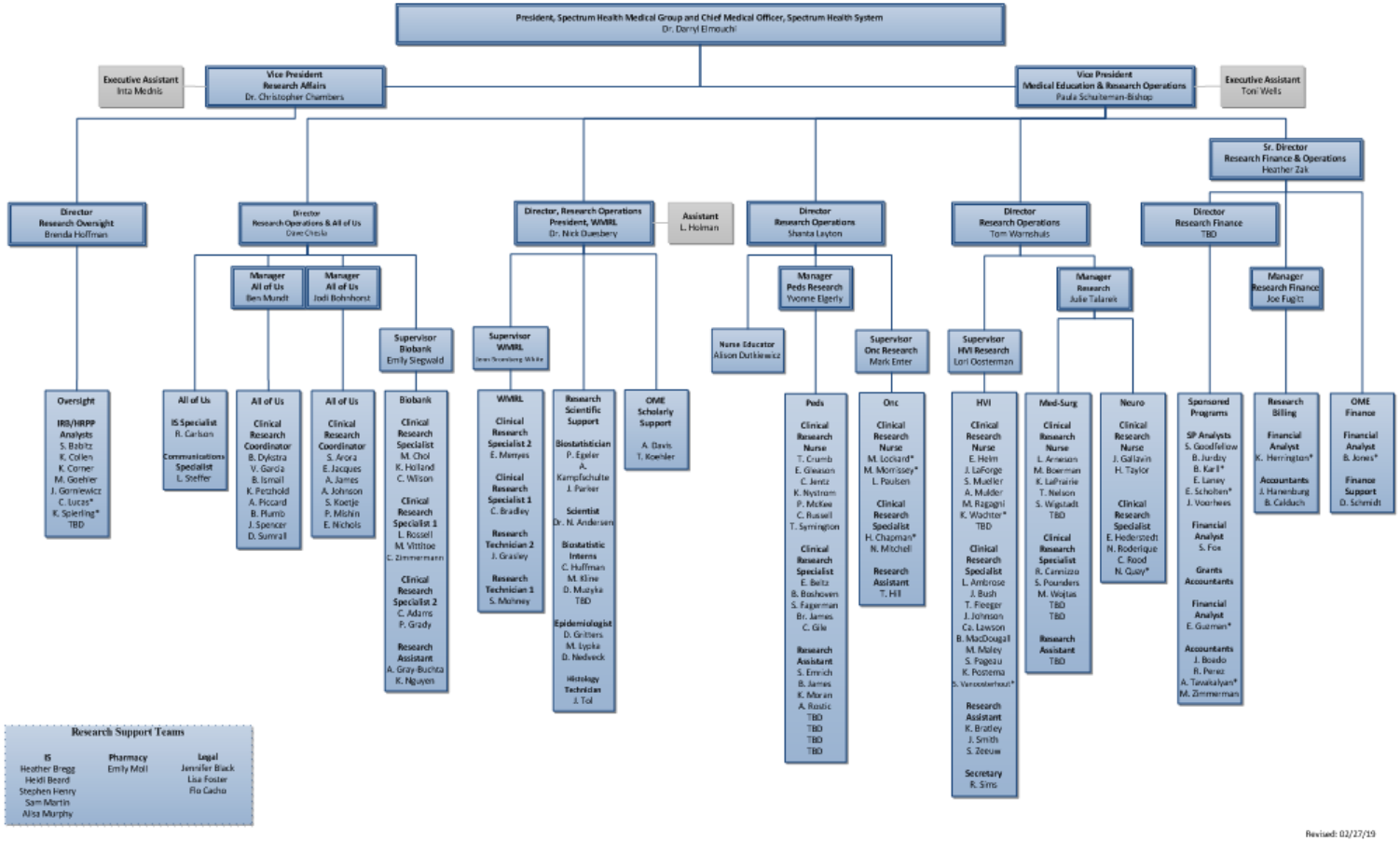
SPECTRUM HEALTH OFFICE OF RESEARCH



Our PI Journey at SHOR

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‘We need to get organized’

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Process Improvement 1.0 (April 2017)

DASHBOARD						
	Areas	Project Lead	Exec. Sponsor	Due	Status	Updated
Financial Sustainability						
Integrated CSL Reporting	Res. Fin./Clin.Ops	Megan/Tom	Chris C.	5/1/2018		3/28/2018
Research Metrics and Tracking	All	Nick D.	Chris C.	9/1/2018		4/10/2018
Business Development	Shanta/Dave/Nick/Megan	Dave C.	Chris C.	9/30/2018		8/23/2017
Vetting/Feasibility System	Clin. Ops/IS	Shanta L.	Chris C.	1/1/2018		4/11/2018
Workflows and Processes						
Internal Award Consistency	OSP	Megan/Tom	Heather Z.	6/1/2018		4/11/2018
Integrated Study Closure Template and Pilot	RF/Clin Ops	Megan/Tom	Heather Z.	7/1/2018		4/11/2018
Comprehensive Education Program	Education/RI	Lori O./Monica R.	Shanta/Megan	9/1/2018		4/11/2018
Legal and Regulatory						
Internal Audit (KPMG)	RF	Heather	Chris C.	9/1/2018		3/28/2018
ERP	RF	Heather	Chris C.			3/28/2018
MSU Master Agreement	RI/OSP	Jennifer B./Cara	Chris C.	9/1/2018		7/18/2017
Master agreement with VAI and MSU	RI/OSP	Nick D.	Chris C.	9/1/2018		4/11/2018
Information Services						
Nexus optimization for research	Clin. Ops/IS	Shanta/Megan	Chris C.			3/28/2018
E-Intake Form	OSP/IRB/Clin. Ops	Nick D.	Chris C.	10/15/2017		3/28/2018
ORA IS System Upgrade	OSP/IRB/IS	Tom/Shanta L	Alisa M.	7/1/2018		4/11/2018
Branding and Culture						
Marketing Brochure/Booklet	All	Megan/Shanta/Nick/Dave	Chris C.	9/1/2018		4/11/2018
Display wall	All	Cheryl	Chris C.	9/1/2018		4/11/2018

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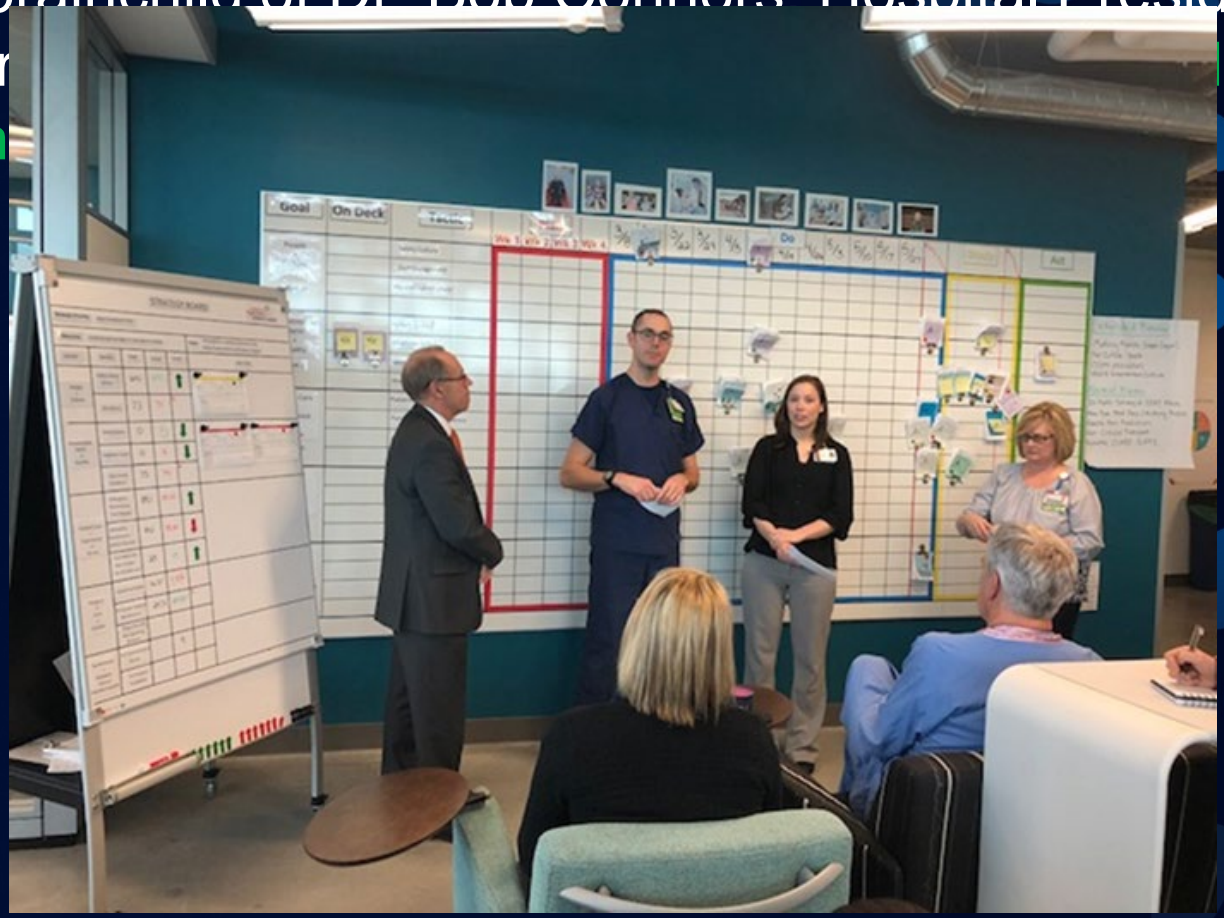
Process Improvement 2.0 – Adopting Kaizen

Introducing HDVCH I Hub ..... process improvement system which was the brainchild of Dr. Bob Connors, Hospital President, and James Cr el and mentorsh



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What is Kaizen?

.....kaizen refers to activities that continuously improve all functions and involve all employees from the CEO to the assembly line workers. It also applies to processes, such as purchasing and logistics, that cross organizational boundaries into the supply chain.[1] It has been applied in healthcare,[2] psychotherapy,[3] life-coaching, government, and banking.

(Wikipedia: https://en.wikipedia.org/wiki/Kaizen)

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Key Features of Improvement Hubs

Encourages individuals to put heads together to come up with solutions that address barriers, inefficiencies and pain points - yay teamwork!

Increases transparency, communication and collaboration thanks to a physical visual management and tracking system tracking. – awareness and collegiality

Supports effective, timely and continuous improvement activity to assist moving an idea to implementation – effective guide

Engages all staff in improvement activity – it's a weekly party!!

Value of Teamwork!

Colleagues who are encouraged and supported to act collaboratively stuck at their task 64% longer than their peers not working in teams, lower fatigue levels and a higher success rate were also noted.

"The results showed that simply feeling like you're part of a team of people working on a task makes people more motivated as they take on challenges," the researchers say.

https://www.forbes.com/sites/adigaskell/2017/06/22/new-study-finds-that-collaboration-drives-workplace-performance/#2e90221a3d02

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Definitions

RiHub The Tool – WHAT IS IT

- Research improvement Hub
- Centralized, **team based** model to support improvement efforts, with built in mentorship and comraderie
- Lanes based on our four key strategies – Drive, Lead, Transform and Grow.
- Executive sponsorship from leaders in SHOR
- Visual, weekly management system

Methodology – HOW DOES IT WORK

- A3 Thinking/Document – systematic format for planning out the project
- Plan/Do/Study/Act cycle for life of project (90-120 days)
- Continual reporting out of progress and barriers to whole community

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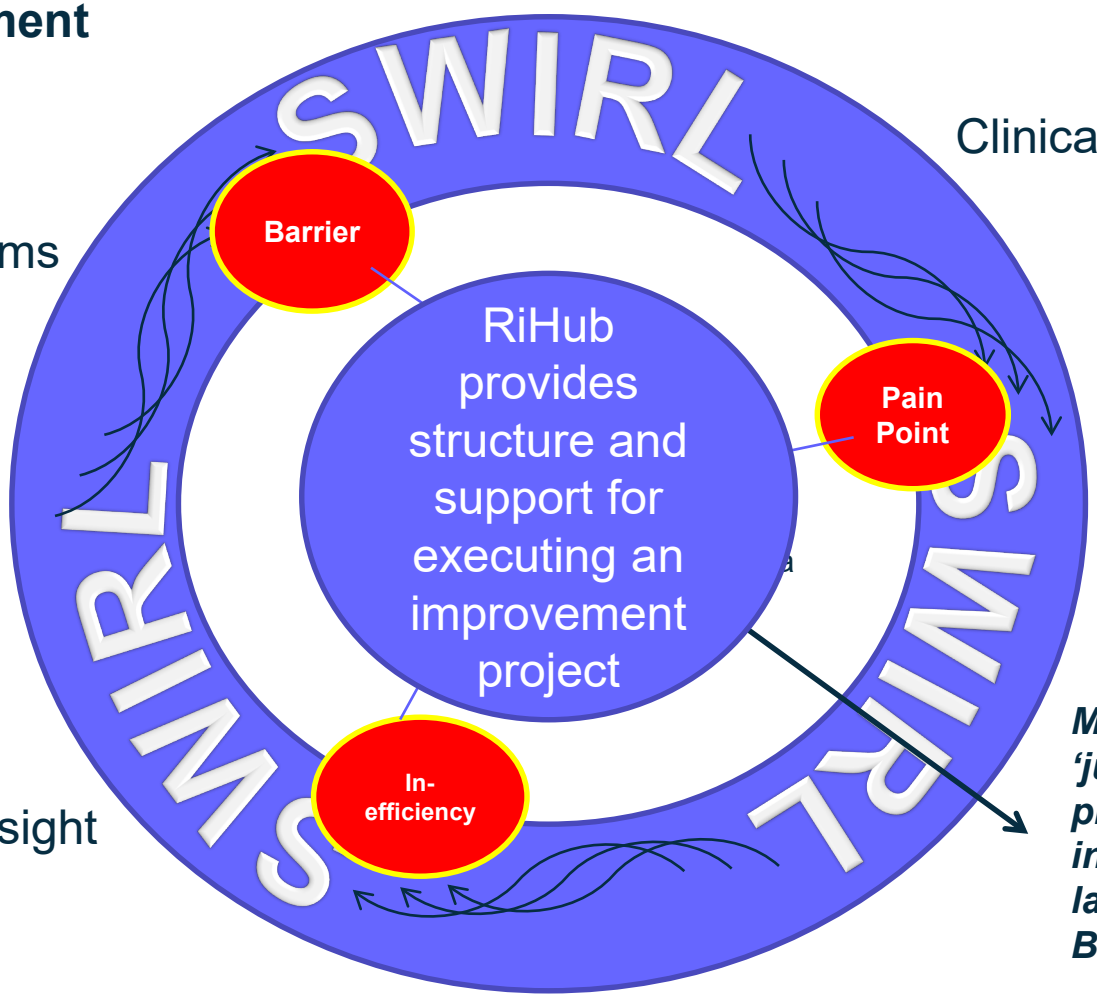
RiHub – How it Works

Complex Department



Clinical Operations

Finance

Sponsored Programs

Scientific Support

Research Oversight

More than a local 'just do it'/small project, and fits into a strategic lane on the RiHub Board

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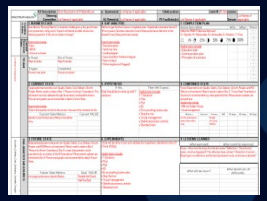
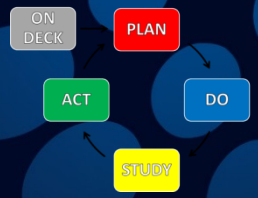
The RiHub Process Pictorially



Process Improvement Idea → *Identify Executive Sponsor and Co-Improvers* → *Submit an intake ticket/place on "On Deck"* → *A 3 Development (RiHub A3 Champions can assist)* → PDSA Cycle Experiments → *Periodic Reports to weekly iHub meeting*



New, improved process is adopted (or not)

RiHub Board and the Lanes

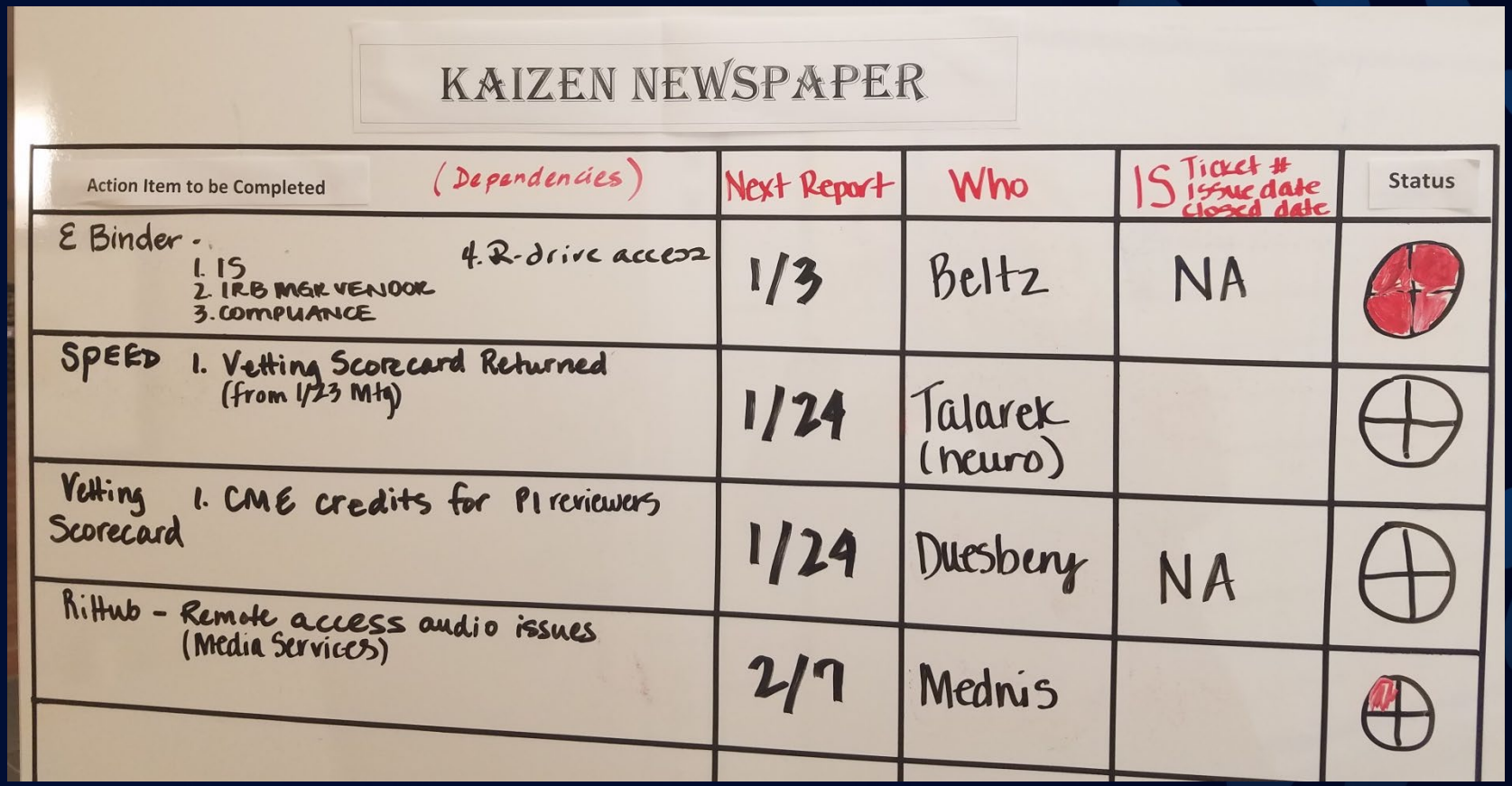
Visual management system

Lanes that align with department strategy

Dates for reporting progress to whole audience

GOAL	RiHub Spectrum Health Office of Research innovation/improvement/idea Hub	ON DECK A3 Boxes 1-3	PLAN A3 Boxes 4-7			DO											STUDY A3 Box 8	ACT
			11/1	11/8	11/15	11/29	12/6	12/13	12/20	12/27	1/3	1/10	1/17	1/24	1/31	2/7	2/14	
DRIVE	Personal satisfaction and professional development of our team (Brenda Hoffman)																	
	Collaborations with the greater research community (Heather Zak)																	
	A cadence of accountability (Tom Warnshuis)																	
TRANSFORM	Our infrastructure to support precision medicine and genomics (Dave Chesla)																	
	Our capabilities to support complex clinical trials (Shanta Layton)																	
	Our research priorities to promote financial sustainability (Tom Warnshuis)																	
GROW	A culture of excellence, diversity, and inclusivity (Brenda Hoffman)																	
	Mentorship for development of clinical researchers (Nick Duesbery)																	
	Community awareness of research at Spectrum Health (Heather Zak)																	
LEAD	By developing new health solutions and opportunities for patient access to clinical research (Dave Chesla)																	
	By applying for our own funding (Nick Duesbery)																	
	By guiding changes to support research, system integration, and process improvement (Shanta Layton)																	

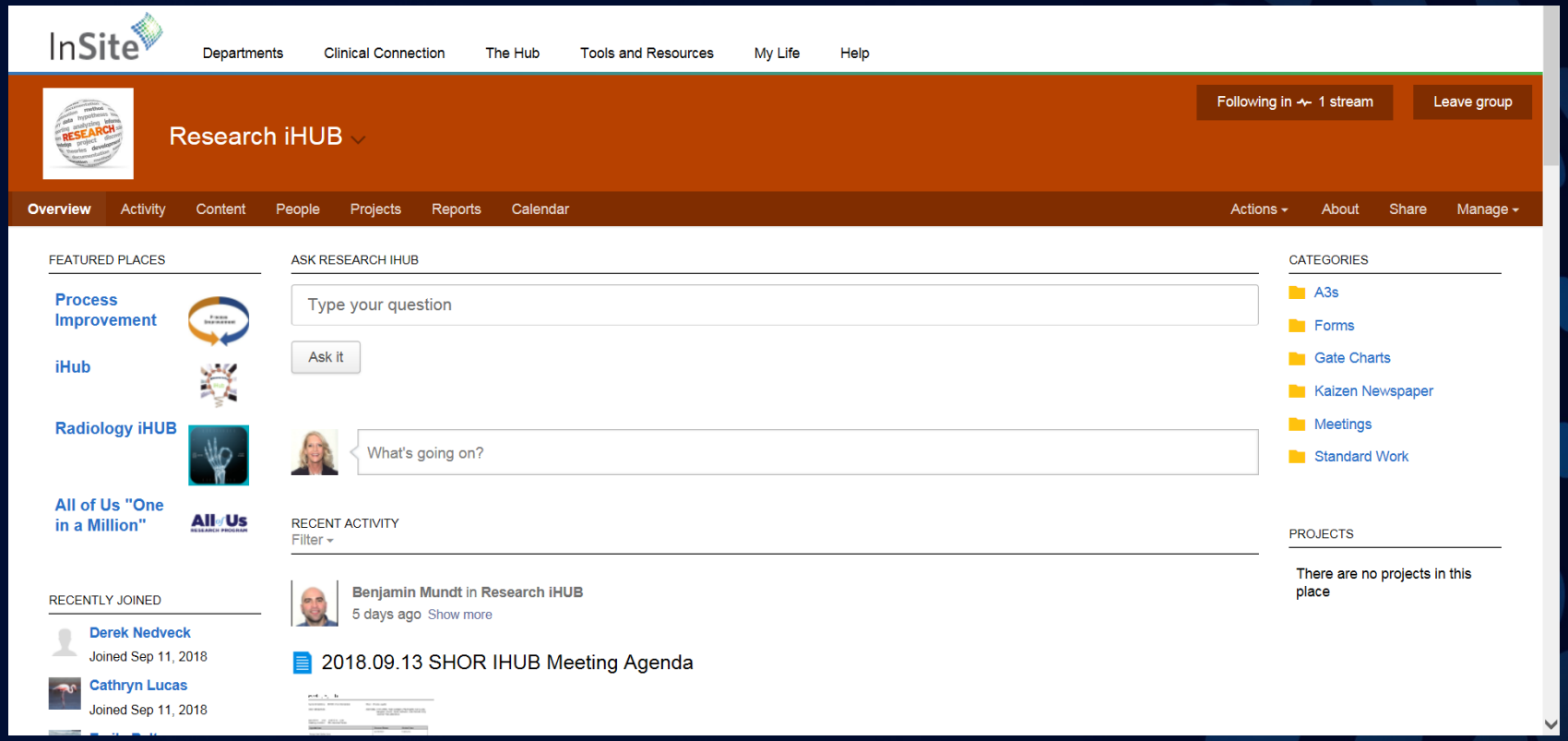
Kaizen Newspaper – The Barrier/Dependencies Tracker



KAIZEN NEWSPAPER

Action Item to be Completed (Dependencies)	Next Report	Who	IS Ticket # issue date closed date	Status
E Binder - 1. IS 2. IRB MGR VENDOR 3. COMPLIANCE 4. R-drive access	1/3	Beltz	NA	
SPEED 1. Vetting Scorecard Returned (from 1/23 Mtg)	1/24	Talarek (neuro)		
Vetting Scorecard 1. CME credits for PI reviewers	1/24	Duesbery	NA	
Rithub - Remote access audio issues (Media Services)	2/7	Mednis		

Communications about RiHub



Weekly email with assignments and projects listed
4 Catalyst Members who are go to staff for submitting projects

The Weekly Meetings

Communicating progress on process improvement tasks is key!

Normal project report = 1 min; Extended project report = 3 min

Report out successes, metrics, and barriers.

When: Thursdays at 9:00 a.m.
(first session 11/1/2018)

Where: Secchia 7th floor Café

Who: All staff

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RiHub is Real!

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10 minute break followed by a deeper dive into the tool, and our own PI project!

The A3 Document

Tool for learning about, thinking, planning, and experimenting with new or existing processes.

Clearly defines expectations for project and completion

Gives us a structure and guidance during the PDSA cycle

Let's take a tour…

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Parts of an A3

Team members	*Project owners*		
	1. Business Case	4. Gap Analysis	7. Completion Plan
	2. Current State	5. Predictions	8. Confirmed State
	3. Future State	6. Experiments	9. Lessons Learned

Parts of an A3 – Box 1 Business Case

Team members

Project owners

1. Busi

1. BUSINESS CASE	
Describe the "Burning Platform" or business challenge (e.g. low growth rates, poor productivity, rising costs). Support with data if possible. Answer the following question: 1) Why do we need to change? Useful tools include: • Data • SIPOC • Voice of customer	
In Scope	Out of Scope
Major Includes	Major Excludes
Trigger	Completed
Process start point	Process end point

Box 2 – Current State

Team members

Project owners

1. Bu

2. Cu

2. CURRENT STATE

Target performance metrics set: Quality, Safety, Cost, Delivery, Growth, People. Metrics need to relate to Box 1, "Reason for Action" (mandatory). The information must be validated through observations and baseline metrics. Pictures and graphs are recommended to depict Current State.

Useful tools include:

- Due to the quantity of tools for this section, they are in the comment for this field.

Current State Metrics	Current VALUE
Identify Current Performance Metrics that tell the story.	

Box 3 – Future State

Team members

3. FUTURE STATE

Balanced performance measures set: Quality, Safety, Cost, Delivery, Growth, People, and ROI (Return on Investment). Metrics need to relate to Box 1, "Reason for Action" (mandatory). Box 3 is static during reviews and is populated only at creation of the A3 (mandatory). Measurement updates are entered into Box 8. Pictures and graphs are recommended to depict Future State.

Useful tools include:

- Achievable attributes (SMART Goals)

Future State Metrics	Goal VALUE
List target performance. Identify Metrics.	Double the Good, Half the Bad

Box 4 – Gap Analysis

Project owners

Team members

4. GAP ANALYSIS

Method to get the Root Cause is completely open. Graphically summarize the top 5-10 root causes. Describe where the Current State performance falls short of the desired Future State performance levels.

Useful tools include:

- Time obsevations
- Takt/Cycle Time
- Loading diagram
- Cause and effect / fishbone diagram
- Pareto analysis
- 5 Whys (regular and 3 legged)

Box 5 - Hypothesis

Team members

Project owners

5. HYPOTHESIS	
If We...	Then We Expect...
1 Goal should be to come up with 7 solutions	Useful tools include: • 7 Solutions • Flow • Pull • 6S • Error proofing / poke-yoke • Stop the line • Visual management • Statistical process controls • Standard work

3. Future State

Box 6 - Experiments

Team members

6. EXPERIMENTS

What will be done to test and validate the hypothesis identified in Box 5? (Think PDSA).

Useful tools include:

- 7 Solutions
- Flow
- Pull
- 6S
- Error proofing / poke-yoke
- Stop the line
- Visual management
- Statistical process controls
- Standard work

3. Future State

6. Experiments

Box 7 – Completion Plan

Project owners

etion Plan

7. COMPLETION PLAN

Action Item-What	Who	When	Status
Utilize the SMART Objective Approach. S = Specific, M = Measurable, A = Achievable, R = Realistic, T= Time. ○ 0% ◔ 25% ◑ 50% ◕ 75% ● 100%			
Useful tools include: • Education plan • Communication plan • Principles of execution			

Box 9 – Confirmed State

Project owners

8. CONFIRMED STATE

Future State metrics set: Quality, Safety, Cost, Delivery, Growth, People, and ROI (Return on Investment). Metrics need to relate to Box 3, "Future State" (mandatory). A picture is recommended (e.g. clear graphs/trends). Measurement updates are entered here.

Useful tools include:

- MDI with Golden Tickets
- Visual management
- Kamishibai (K-Cards)

Metrics	Current	Future	RIE	30 days	60 days	90 days
List the performance metrics that tell the story.		Double the Good, Half the Bad				

etion Plan

med State

3. Future State

6. Experiments

Box 9 – Lessons Learned

Team members

9. LESSONS LEARNED	
What went well…	*What could be improved…*
Issues - What were the issues from the last review? Reflections - Since the last review, what has happened? How effective have we been? Retentions / Lessons - Based upon our reflections and the last improvement cycle, what have we learned?	
What did we learn?	*What would you do differently…*

n Plan

d State

3. Future State | 6. Experiments | 9. Lessons Learned

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RiHUB A3

A3 Description:	RiHub Development	Exec. Sponsor(s):	Chris Chambers	Site/Location:	15 W. Michigan/Secchia	Event #	1	Revision:	
Steering Committee:	Shanta Layton, Tom Warnshuis, Cat Lucar, Nick Duesbery, Emily Boltz, Katy Wachter, Derek Nedvek, Ben Mundt	A3 Owner(s):	Shanta Layton, Tom Warnshuis, Nick Duesbery	PI Facilitator(s):	Shanta Layton			Sensei:	

Creation Date: 7/1/2018

TEAM: RiHub Committee

1. BUSINESS CASE

A focus on continual process improvement is integral to Spectrum Health providing the best care for our patients, but also in engaging in impactful research to improve their care. Less than 20% of the improvement projects in SHOR reach completion due to:
- lack of a cadence of accountability
- unsustainability in improvement efforts by relying solely on leadership
- lack of integration with strategic planning

In Scope	Out of Scope
Definition and execution of improvement system for SHOR	Specific improvement projects or specific research projects

Trigger	Completed
Recognition that we need a more formal improvement system	The new improvement system is designed and launched

2. CURRENT STATE

Individual departments within SHOR have identified areas for improvement, but work is not coordinated across teams, and therefore fails to thrive. Adding to the difficulty is that teams do not share a common improvement method or language. Project prioritization is often unclear, and projects often start but barriers preventing them from being completed are not adequately addressed.

Current State Metrics	Current VALUE
% of projects submitted by non management	0
# of projects submitted/month	100%
Time to project completion	90 days

3. FUTURE STATE

Improvement projects are clearly focused on the SHOR strategic goals set forth by leadership. Improvement projects are designed based on the scientific method, they are data driven, and their results are studied and used to implement process improvements. There is a clear and defined structure to how improvement projects are completed, using the PDSA cycle, tracking their progress in an A3 document, and having visual accountability and department-wide sharing with the iHub board.

Mission: The RiHub is a team-based model to rapidly improve what matters most for the research services we provide to investigators and the operations around studies that most impactful for our patients. It is characterized by: integrated improvement, engagement of staff, and exceptional business outcomes.

Vision: **By November 1, 2018** the RiHub will activate and promote the entire SHOR team towards continuous improvement using the scientific method, frequent learning, and systems thinking

Future State Metrics	Goal VALUE

BALANCED MEASURES

4. GAP ANALYSIS

1) Different areas of SHOR are working independently on improving processes,with rare collaboration with other areas of the department

2) The current dashboard for improvement projects is only handled by leadership and there is no visibility for the rest of the staff. Also, there is no comprehesive visibilty to successes and failures. There has been no sharing of lessons learned or successful improvement stories.

3) A lack of official strategic planning document has created a lack of focus on the current project list. The current projects don't necessarily point to any strategic goal and as such, there is no formal, clear method for aligning improvement work to SHOR strategic and operational priorities.

5. HYPOTHESIS

If We…	Then We Expect…
(1) Create & implement a single, coherent, PDSA-based model for improvement in SHOR	(1) To communicate and provide a standard approach to improvement for all of SHOR.
(2) Clearly define the roles & responsibilities of improvement specialists, leaders, & supporting staff.	(2) To identify who is responsible for each aspect of improvement work.
(3) Develop a method of visually managing the improvement work, including alignment to SHOR strategy	(3) Clearly align to SHOR priorities, clearly identfiy project status and resources, clearly understand what is working and what is not.
(4) Co-locate all resources dedicated to the improvement process."	(4) All improvement resources to work more closely (and thus more effectively) together.

6. EXPERIMENTS

(1) iHub Model Creation -- Integrate Mission & Vision into improvement plan
PDSA-based, Data-Driven, Call to Action, etc... (child A3)
(2) Establish iHub Roles & Responsibilities -- define intake process, cadence, location method for improving iHub as the experiment continues.
(3) Establish iHub Visual Management System -- How will the space facilitate visual management, emphasize "go to gemba", and be accessible to leadership and front-line staff?

7. COMPLETION PLAN

Action Item-What	Who	When	Status
Create structure of the dashboard (buckets/lanes)	Shanta/ Tom?	9/1/2018	
Determine cadence/ location/delivery method for RiHub	PC	9/15/2018	
Launch first RiHub session	PC	11/1/2018	

8. CONFIRMED STATE

Metrics	Current	Future	RIE	30 days	60 days	90 days

9. LESSONS LEARNED

What went well…	What could be improved…
What did we learn…	What would you do differently…

How We Measure Success

Two main aims

- To promote excellence in research administration by adopting cutting edge tools and smart, lean processes, and;
- To enhance department culture by promoting team based all -inclusive problem solving.

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Established Metrics

Metrics of Meetings

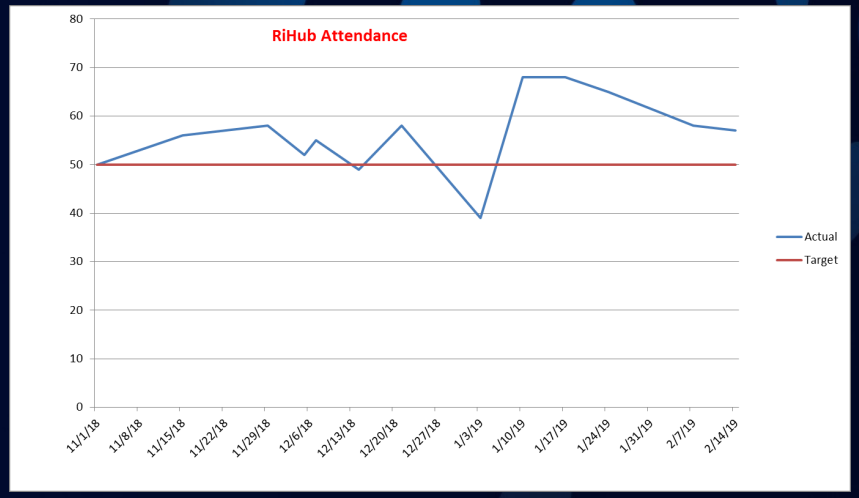
- 50+ in attendance
- ≥2:1 (non-leadership:leadership)
- 2 projects/month (until 20 projects on board)

Metrics of Overall Performance

- Spectrum Esat scores – culture
- Turn around times on study startup activity – improved efficiency
- Improved financial returns

The Numbers – How are we doing?

	Target	1-Nov	8-Nov	15-Nov	22-Nov	29-Nov	5-Dec	7-Dec
Attendees	50	50	53	56	NA	58	52	55
# of Projects on Board	2/month	2	2	2	NA	3	4	4
Non-leader:Leader ratio	≥1:1	0:2	0:2	0:2	NA	1:3	0:2	0:2
Average Proj. completion time	90-120 days	NA	NA	NA	NA	NA	NA	NA



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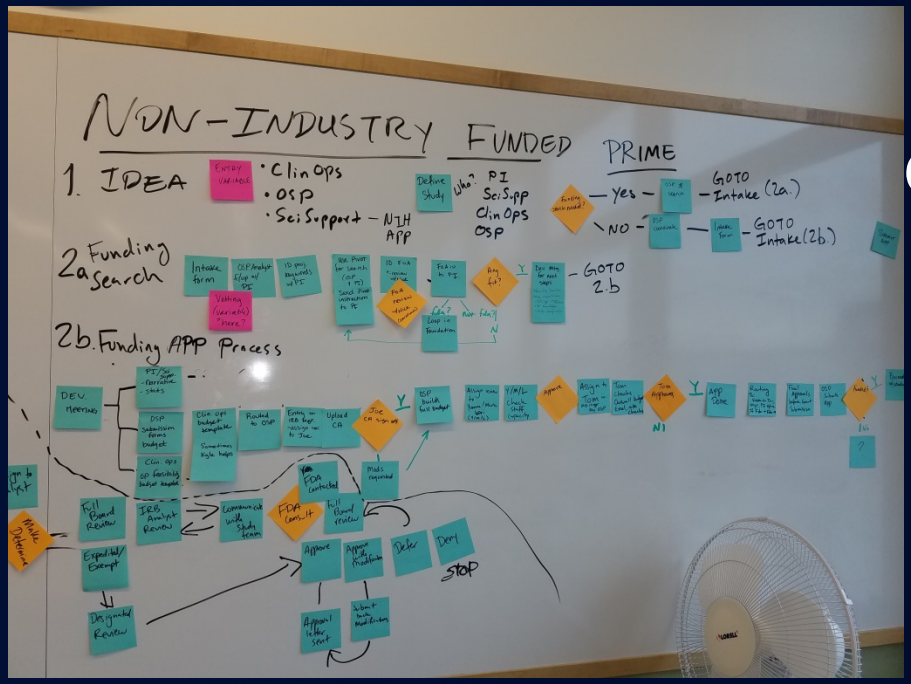
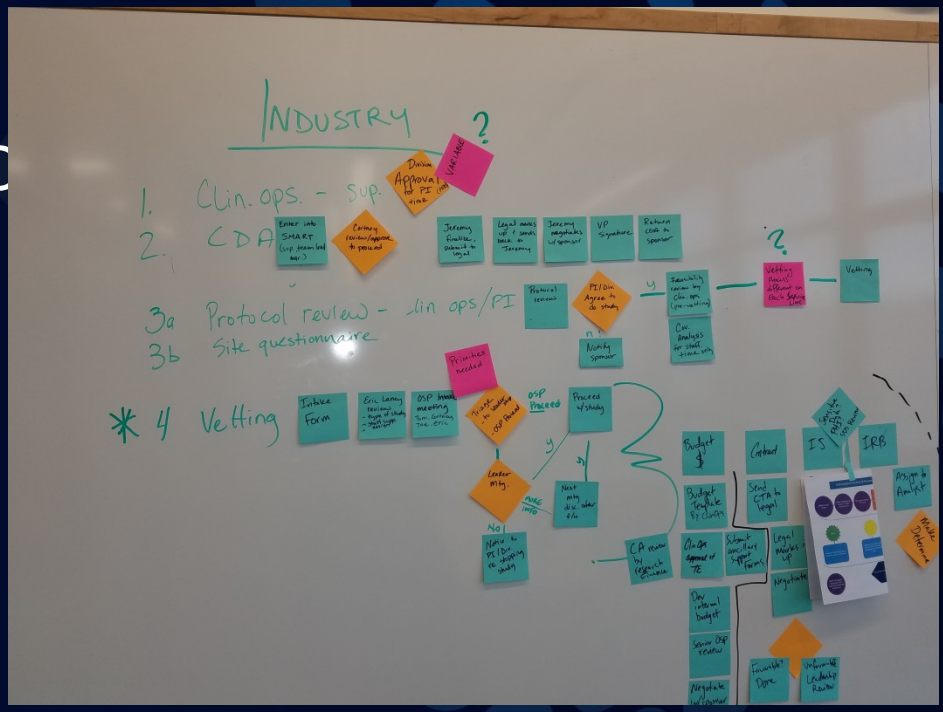
Deeper Dive – Root Cause/Gap Analyses

- Process Mapping





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Deeper Dive – Root Cause/Gap Analyses

Identifying Wastes – TIMPWOOD

Transporting (ie. Not batch shipping specimen samples where possible)

Inventory (ie. Not having supplies needed, or supplies expiring)

Motion (ie. Not batching trips to clinic/lab)

People/Potential (ie. Having nurses making copies/filing)

Waiting (ie. Bottleneck such as legal contracting)

Overprocessing (ie. Too complicated workflow)

Overproducing (ie. Creating too many financial reports)

Defects (ie. protocol deviation)

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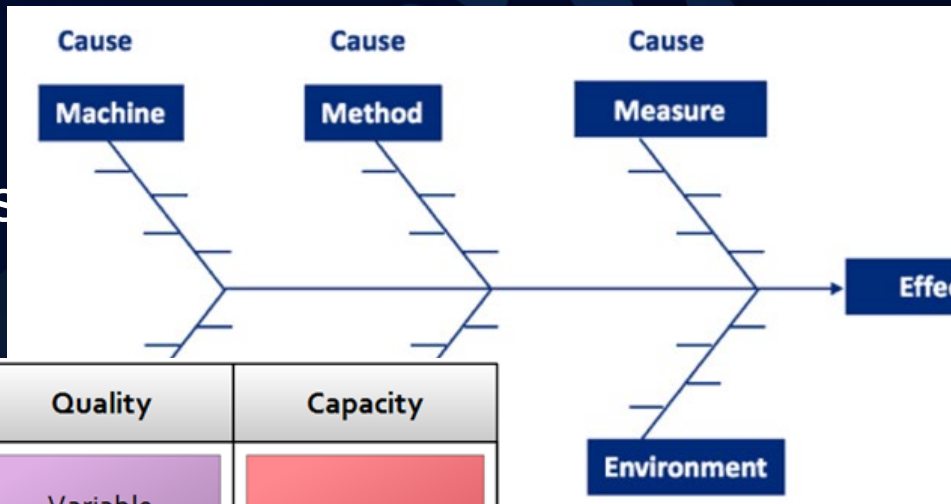
Deeper Dive – Root Cause/Gap Analyses

Fishbone Diagram – Cause and

5 Why's – Find gap, and keep as

Affinity Diagram – chunking chal

Pareto Cha



Staff	Distribution	Quality	Capacity
Lack of staff training	Not enough trucks.	Variable ingredients quality	Insufficient ovens
Difficulties recruiting	Cooling systems in trucks unreliable.	Packaging not strong enough	Limited storage space
High overtime	Product damaged in transit		Seasonal demand

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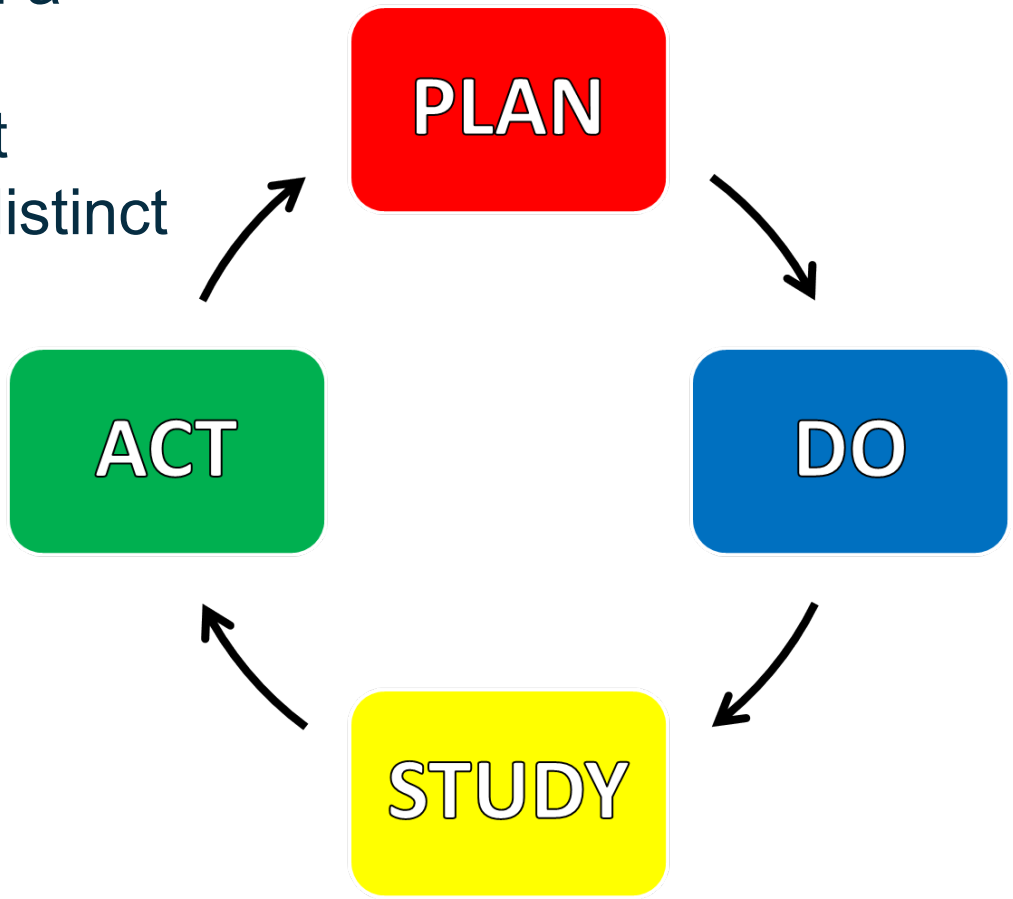
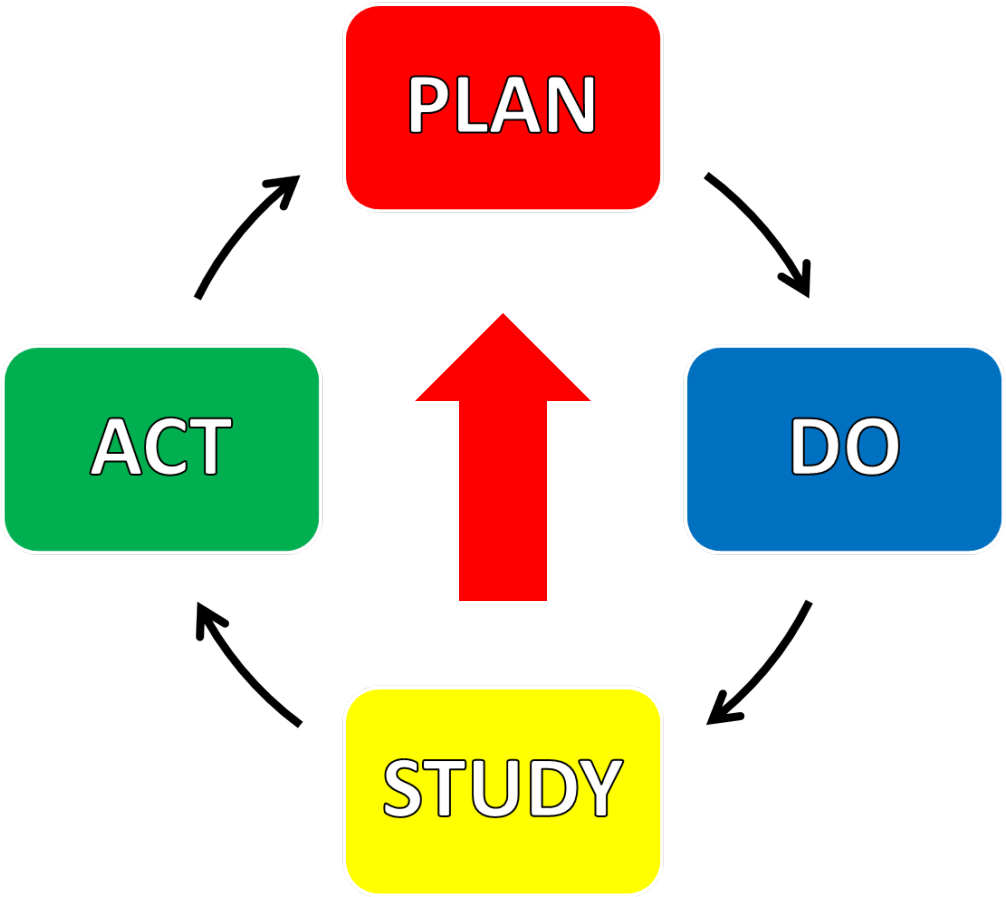
About the PDSA Cycle

Breaks down a process improvement project into distinct phases



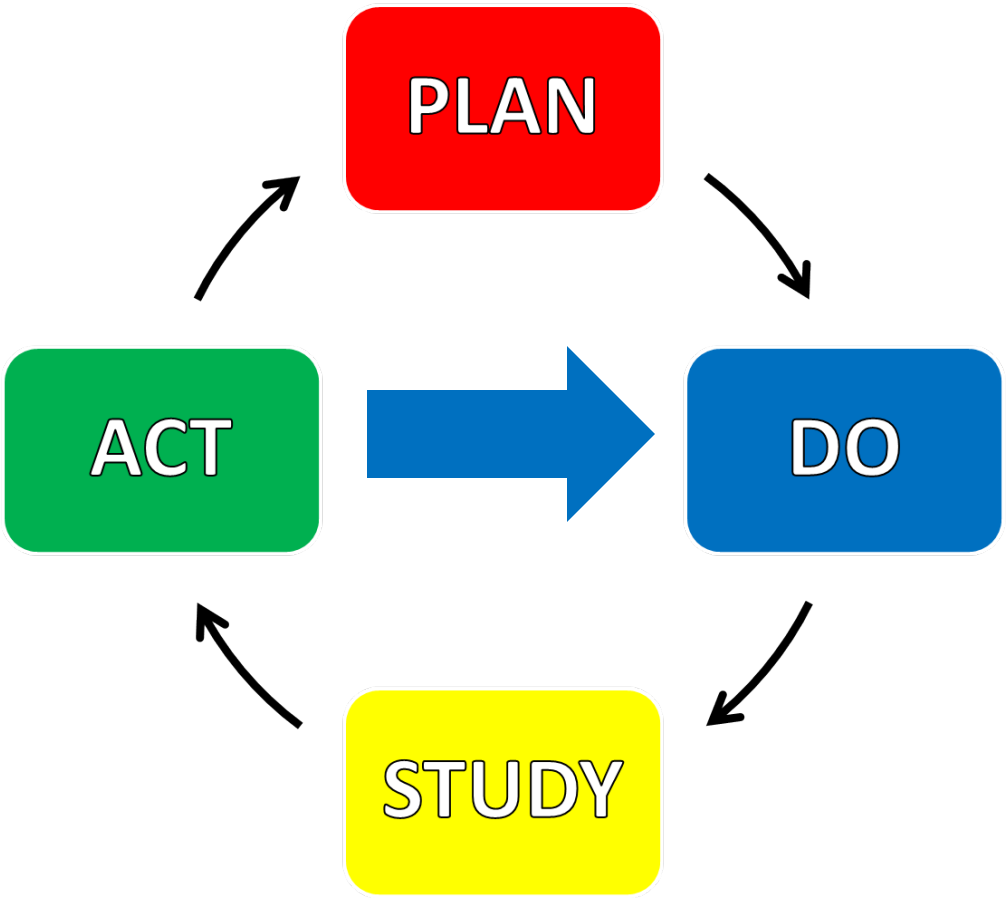
PDSA Cycle - PLAN



What problems are you addressing?

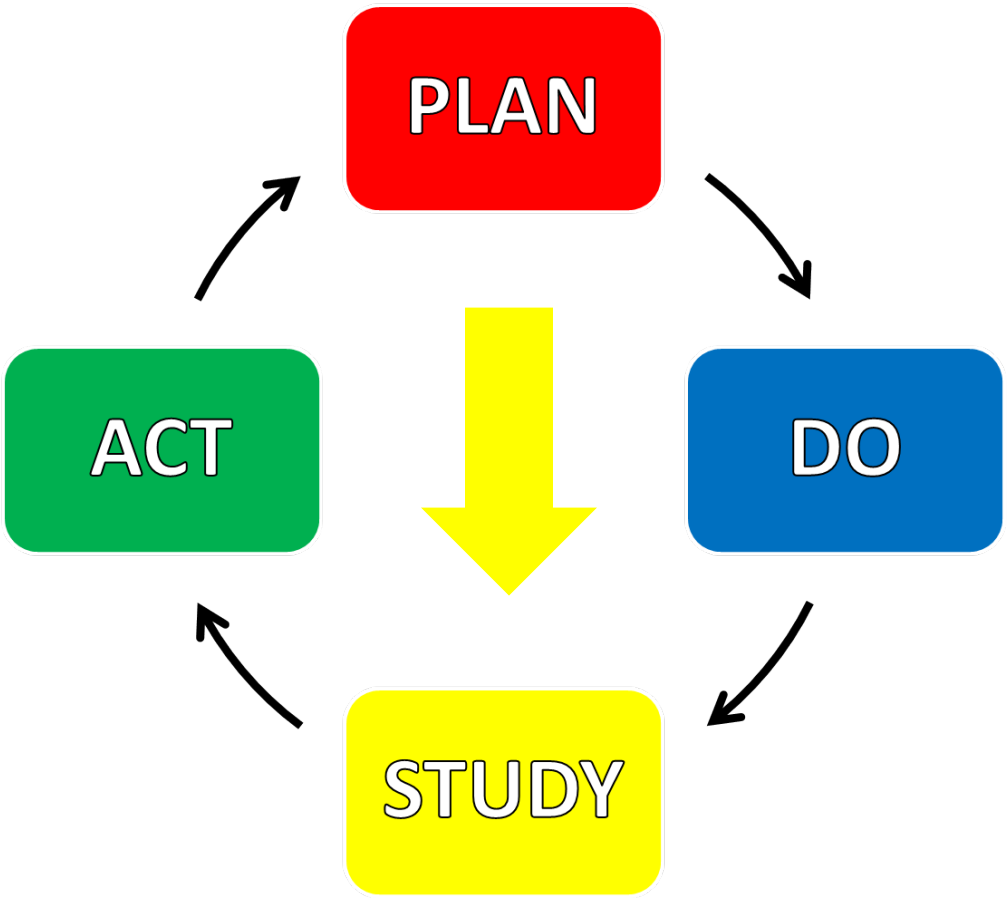
What's the scope, and how will you know you are done?

PDSA Cycle - DO



Complete your planned actions and collect your metrics.

PDSA Cycle - STUDY



Did your actions improve things?

Are there other tests to carry out?

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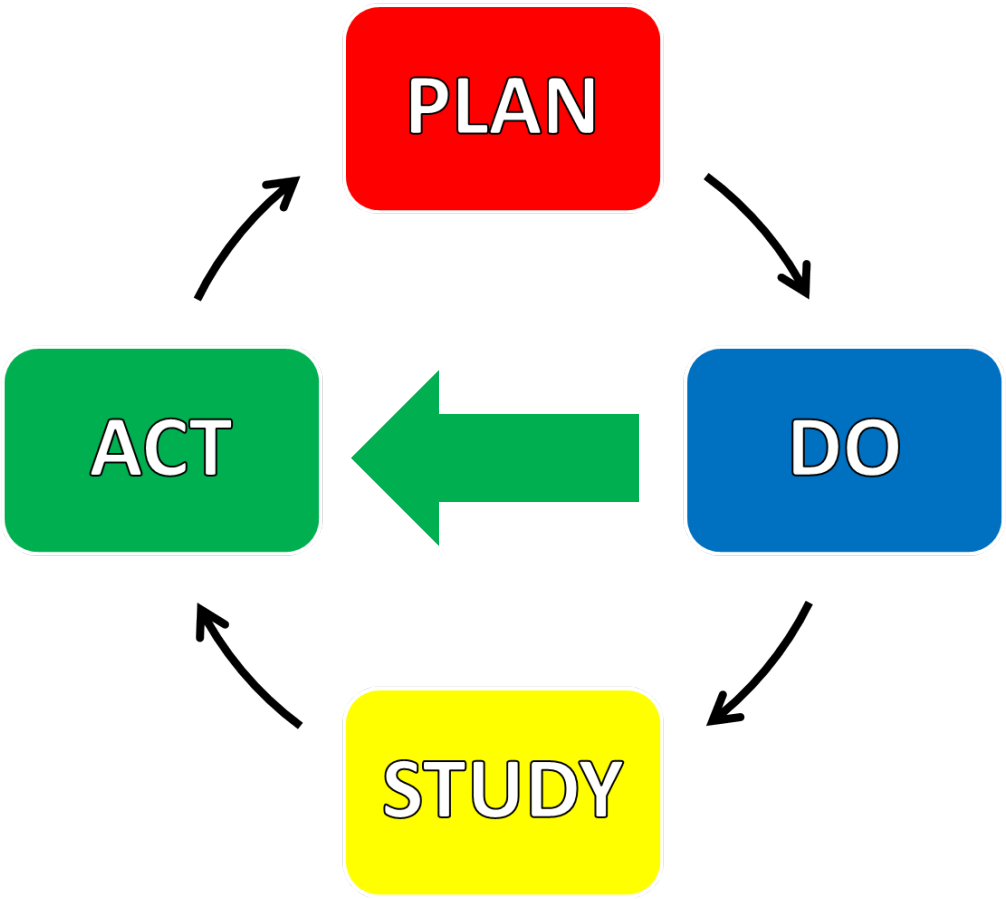
PDSA Cycle - ACT



Implement your new process department wide.

Or, if your process was not improved, design a new test by restarting the PDSA cycle.

Group Activity – Tennis Ball Challenge

10 Volunteers

- 1 time keeper
- 1 ‘counter’
- 8 handlers

Rules:

- Each person must touch every ball, only once
- Balls must all follow same pathway
- 3 attempts to improve

Back to RiHub - Example Projects from SHOR

Project
RiHub
Study Vetting
SPEED
External Ambassador Program
RAPID - Research Program Directory
E-binder (Adult A3)
Crisis communication
CA menu tool

SPEED: To decrease start up time for studies

E-Binder: Move to E-filing clinical trials documents

SPEED Project

SPECTRUM HEALTH	A3 Description:	SPEED	Exec. Sponsor(s):	Shanta Layton	Site/Location:	15 W.	Event #: 1	Revision:
	Steering Committee:		A3 Owner(s):	Jeremy Voorhees	Facilitator(s):	Jeremy Voorhees		Sensei:

Creation Date: 11/27/2018

Current Revision Date:

TEAM: Jeremy Voorhees, Cortney Schaffer, Kyle Herrington, Heidi Taylor

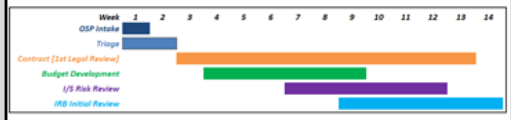
BALANCED MEASURES: Quality, Safety, Cost, Delivery, Growth, People

1. BUSINESS CASE

SHOR's Mission is to create an outstanding culture of support for our researchers, promoting advances in health. We believe a vital piece of that mission is providing confidence to collaborating parties and PI's in our consistency. Our team wants to bring consistency to the startup timeline of Clinical Trials by increasing the maturity of each trial at intake and submitting them into a 1-1-4 request, review, and complete timeline for the big ticket items of startup: budget, risk, IRB, and contract (1st legal review). A mature intake form is one that includes answers to all intake form questions, as well as provides a vetting scorecard, completed budget template including staff time estimates and coverage analsys, sponsor draft package, EDC link and additional technological information if applicable, and classification of data being transferred (i.e. PHI, Limited Data Set, De-

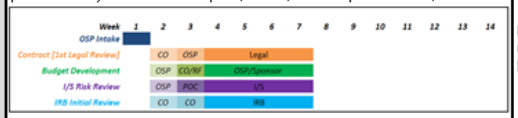
2. CURRENT STATE

When studies comes through intake, they vary in their levels of maturity which requires a multi-week review period to identify and approve, and roughly 6-week completions of budget, risk, IRB, and more for contract (1st legal review) scattered across the startup timeline, as depicted below:



3. FUTURE STATE

When a study comes through intake, it will be mature including answers to all intake form questions, as well as provides a vetting scorecard, completed budget template including staff time estimates and coverage analsys, sponsor draft package, EDC link and additional technological information if applicable, and classification of data being transferred (i.e. PHI, Limited Data Set, De-Identified Data).. It will filter through an expedited intake review and then be placed directly into our 1-1-4 request, review, and complete timeline, as



1-1-4

4. GAP ANALYSIS

1) Sponsors contact Spectrum Health seeking potential collaboration, providing a wide variety of information and document packages, often missing critical items or information.

2) Principal Investigators submit intake forms into IRB Manager with a wide variety of maturity levels, often missing critical items or information.

3) Big ticket startup items are started and completed at different times, making it difficult to estimate how long the startup process will take.

5. HYPOTHESIS

If We_	Then We Expect_
(1) Request a specific and consistent study package from Sponsors, including draft protocols, ICFs, contracts, budgets, CRFs, and EDC links.	(1) There is adequate information to submit a mature intake into IRB Manager;
(2) Enter studies into IRB Manager that are mature at intake, including full sponor study package, vetting scorecard, completed budget template including staff time estimates and coverage analysis.	(2) There is adequate information to fulfill the 1-1-4 request, review, complete timeline goal for all big ticket startup items.
(3) Fulfill 1-1-4 request, review, complete timeline goal for all big ticket startup items.	(3) To enhance SHOR efficiencies in the study startup process thereby increasing our pace of startup and decreasing avoidable delays.

6. EXPERIMENTS

(1) Create a Sponsor Package Request form that will be presented to all Sponsors seeking to perform research with our site, identifying all required pieces of information and documentation needed to initiate our study startup process.

(2) Create a Mature Intake Package – Requirement List to identify all required pieces of information and documentation in order to submit an intake into IRB Manager to initiate our study development process.

(3) Require 1-1-4: 1 week requests, 1 week reviews, 4 weeks completions, for all big ticket startup items including budget negotiation, risk review, IRB approval, and first legal contract review.

7. COMPLETION PLAN

Action Item-What	Who	When	Status
Develop Process	Full squad	1/1/2019	
Test Study	Full squad	3/22/2019	
Educate Key Stakeholders	Full squad	4/4/2019	
Roll out	Full squad	4/11/2019	

8. CONFIRMED STATE

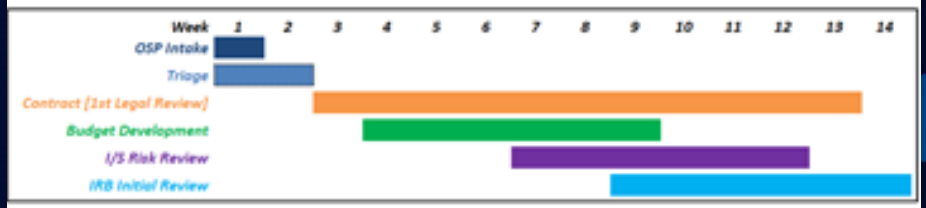
9. LESSONS LEARNED

SPECTRUM HEALTH

SPEED Project

2. CURRENT STATE

When studies comes through intake, they vary in their levels of maturity which requires a multi-week review period to identify and approve, and roughly 6-week completions of budget, risk, IRB, and more for contract (1st legal review) scattered across the startup timeline, as depicted below:



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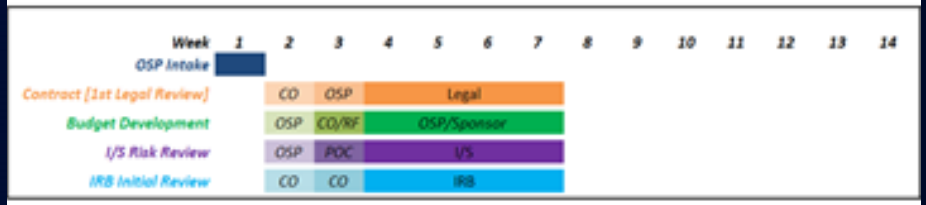
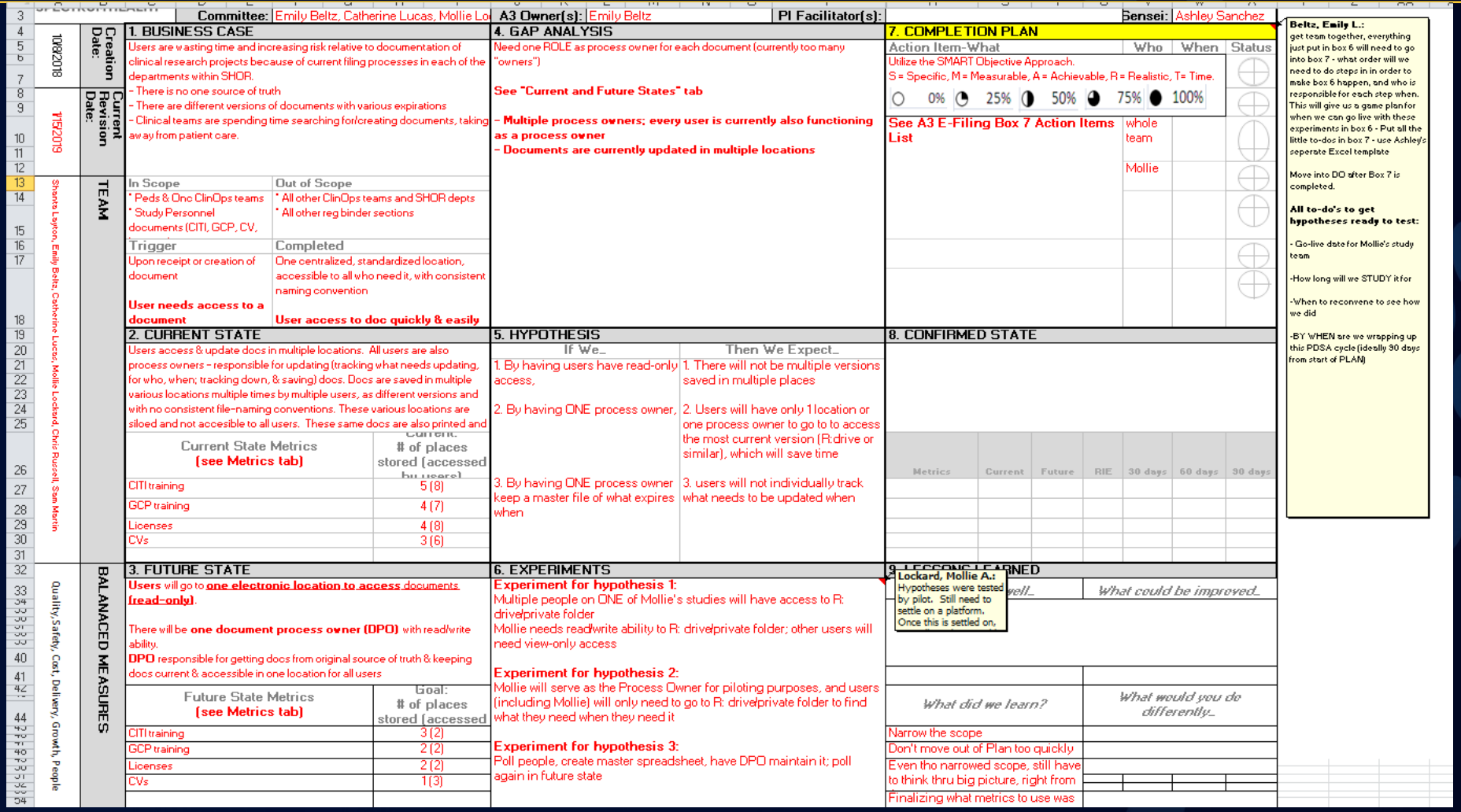


SPECTRUM HEALTH

E-Binder Project



Committee: Emily Beltz, Catherine Lucas, Mollie Lo | A3 Owner(s): Emily Beltz | PI Facilitator(s): | Sensei: Ashley Sanchez

Creation Date: 10/8/2018 | Current Revision Date: 11/5/2019 | TEAM: Shanta Layton, Emily Beltz, Catherine Lucas, Mollie Lockard, Chris Russell, Sam Martin | BALANCED MEASURES: Quality/Safety, Cost, Delivery, Growth, People

1. BUSINESS CASE

Users are wasting time and increasing risk relative to documentation of clinical research projects because of current filing processes in each of the departments within SHOR.
- There is no one source of truth
- There are different versions of documents with various expirations
- Clinical teams are spending time searching for/creating documents, taking away from patient care.

In Scope	Out of Scope
* Peds & Onc ClinOps teams * Study Personnel documents (CITI, GCP, CV,	* All other ClinOps teams and SHOR depts * All other reg binder sections
Trigger	**Completed**
Upon receipt or creation of document **User needs access to a document**	One centralized, standardized location, accessible to all who need it, with consistent naming convention **User access to doc quickly & easily**

2. CURRENT STATE

Users access & update docs in multiple locations. All users are also process owners - responsible for updating (tracking what needs updating, for who, when; tracking down, & saving) docs. Docs are saved in multiple various locations multiple times by multiple users, as different versions and with no consistent file-naming conventions. These various locations are siloed and not accesible to all users. These same docs are also printed and

Current State Metrics **(see Metrics tab)**	Current: # of places stored (accessed by users)
CITI training	5 (8)
GCP training	4 (7)
Licenses	4 (8)
CVs	3 (6)

3. FUTURE STATE

Users will go to **one electronic location to access** documents **(read-only)**.

There will be **one document process owner (DPO)** with read/write ability.
DPO responsible for getting docs from original source of truth & keeping docs current & accessible in one location for all users

Future State Metrics **(see Metrics tab)**	Goal: # of places stored (accessed
CITI training	3 (2)
GCP training	2 (2)
Licenses	2 (2)
CVs	1 (3)

4. GAP ANALYSIS

Need one ROLE as process owner for each document (currently too many "owners")

See "Current and Future States" tab

- Multiple process owners; every user is currently also functioning as a process owner
- Documents are currently updated in multiple locations

5. HYPOTHESIS

If We_	Then We Expect_
1. By having users have read-only access,	1. There will not be multiple versions saved in multiple places
2. By having ONE process owner,	2. Users will have only 1 location or one process owner to go to to access the most current version (R:drive or similar), which will save time
3. By having ONE process owner keep a master file of what expires when	3. users will not individually track what needs to be updated when

6. EXPERIMENTS

Experiment for hypothesis 1:
Multiple people on ONE of Mollie's studies will have access to R: drive/private folder
Mollie needs read/write ability to R: drive/private folder; other users will need view-only access

Experiment for hypothesis 2:
Mollie will serve as the Process Owner for piloting purposes, and users (including Mollie) will only need to go to R: drive/private folder to find what they need when they need it

Experiment for hypothesis 3:
Poll people, create master spreadsheet, have DPO maintain it; poll again in future state

7. COMPLETION PLAN

Action Item-What	Who	When	Status
Utilize the SMART Objective Approach. S = Specific, M = Measurable, A = Achievable, R = Realistic, T= Time. ○ 0% ◔ 25% ◑ 50% ◕ 75% ● 100%			
See A3 E-Filing Box 7 Action Items List	whole team		
	Mollie		

8. CONFIRMED STATE

Metrics	Current	Future	RIE	30 days	60 days	90 days

9. LESSONS LEARNED

Lockard, Mollie A.: Hypotheses were tested by pilot. Still need to settle on a platform. Once this is settled on,

What went well_	What could be improved_

What did we learn?	What would you do differently_
Narrow the scope	
Don't move out of Plan too quickly	
Even tho narrowed scope, still have to think thru big picture, right from	
Finalizing what metrics to use was	

Beltz, Emily L.: get team together, everything just put in box 6 will need to go into box 7 - what order will we need to do steps in in order to make box 6 happen, and who is responsible for each step when. This will give us a game plan for when we can go live with these experiments in box 6 - Put all the little to-dos in box 7 - use Ashley's seperate Excel template

Move into DO after Box 7 is completed.

All to-do's to get hypotheses ready to test:

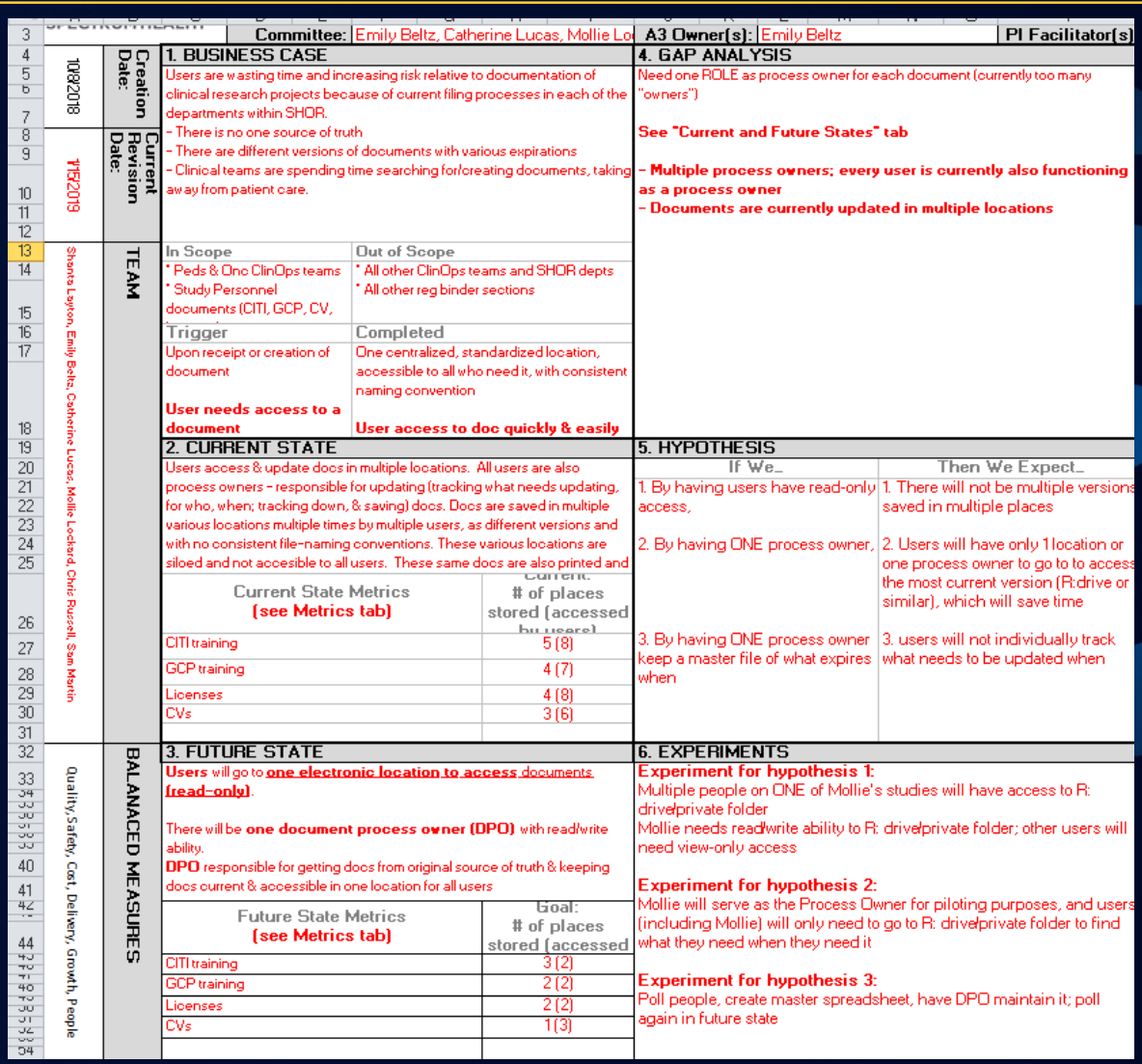
- Go-live date for Mollie's study team

-How long will we STUDY it for

-When to reconvene to see how we did

-BY WHEN are we wrapping up this PDSA cycle (ideally 30 days from start of PLAN)

E-Binder - Project



	Committee: Emily Beltz, Catherine Lucas, Mollie Lo		A3 Owner(s): Emily Beltz	PI Facilitator(s)
10/8/2018	Creation Date:	1. BUSINESS CASE	4. GAP ANALYSIS	
		Users are wasting time and increasing risk relative to documentation of clinical research projects because of current filing processes in each of the departments within SHOR. - There is no one source of truth - There are different versions of documents with various expirations - Clinical teams are spending time searching for/creating documents, taking away from patient care.	Need one ROLE as process owner for each document (currently too many "owners") **See "Current and Future States" tab** **- Multiple process owners; every user is currently also functioning as a process owner** **- Documents are currently updated in multiple locations**	
1/15/2019	Current Revision Date:			
Shanta Layton, Emily Beltz, Catherine Lucas, Mollie Lockford, Chris Russell, Sam Martin	TEAM	In Scope: * Peds & Onc ClinOps teams * Study Personnel documents (CITI, GCP, CV,	Out of Scope: * All other ClinOps teams and SHOR depts * All other reg binder sections	
		Trigger: Upon receipt or creation of document **User needs access to a document**	Completed: One centralized, standardized location, accessible to all who need it, with consistent naming convention **User access to doc quickly & easily**	
		2. CURRENT STATE	5. HYPOTHESIS	
		Users access & update docs in multiple locations. All users are also process owners - responsible for updating (tracking what needs updating, for who, when; tracking down, & saving) docs. Docs are saved in multiple various locations multiple times by multiple users, as different versions and with no consistent file-naming conventions. These various locations are siloed and not accesible to all users. These same docs are also printed and	If We_: 1. By having users have read-only access, 2. By having ONE process owner, 3. By having ONE process owner keep a master file of what expires when	Then We Expect_: 1. There will not be multiple versions saved in multiple places 2. Users will have only 1 location or one process owner to go to to access the most current version (R:drive or similar), which will save time 3. users will not individually track what needs to be updated when
		Current State Metrics (see Metrics tab) / Current: # of places stored (accessed by users)		
		CITI training: 5 (8)		
		GCP training: 4 (7)		
		Licenses: 4 (8)		
		CVs: 3 (6)		
Quality, Safety, Cost, Delivery, Growth, People	BALANACED MEASURES	3. FUTURE STATE	6. EXPERIMENTS	
		Users will go to **one electronic location to access** documents **(read-only)**. There will be **one document process owner (DPO)** with read/write ability. **DPO** responsible for getting docs from original source of truth & keeping docs current & accessible in one location for all users	**Experiment for hypothesis 1:** Multiple people on ONE of Mollie's studies will have access to R: drive/private folder Mollie needs read/write ability to R: drive/private folder; other users will need view-only access **Experiment for hypothesis 2:** Mollie will serve as the Process Owner for piloting purposes, and users (including Mollie) will only need to go to R: drive/private folder to find what they need when they need it **Experiment for hypothesis 3:** Poll people, create master spreadsheet, have DPO maintain it; poll again in future state	
		Future State Metrics (see Metrics tab) / Goal: # of places stored (accessed		
		CITI training: 3 (2)		
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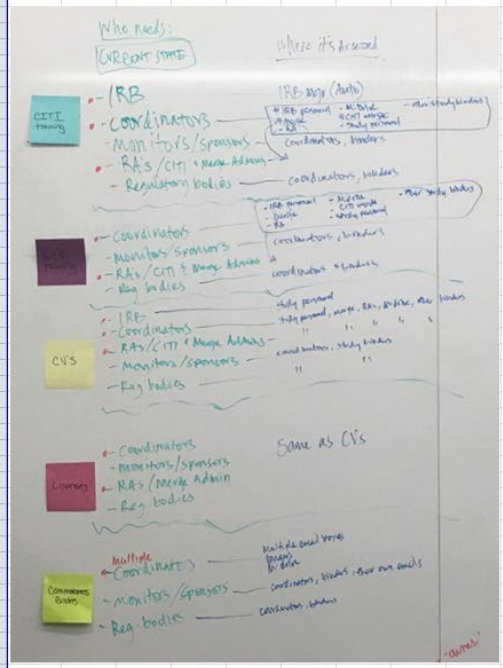
		Licenses: 2 (2)		
		CVs: 1 (3)		

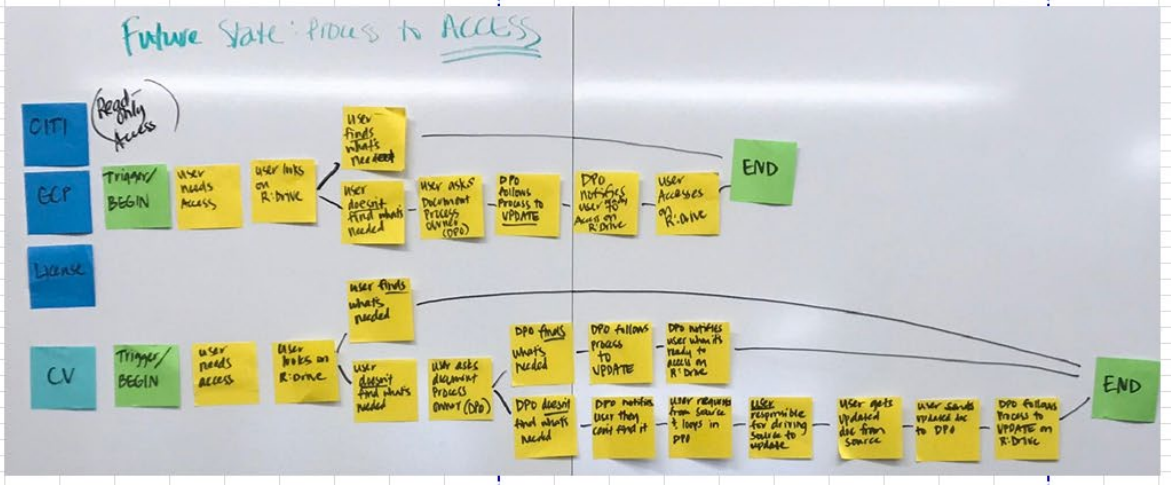
SPECTRUM HEALTH

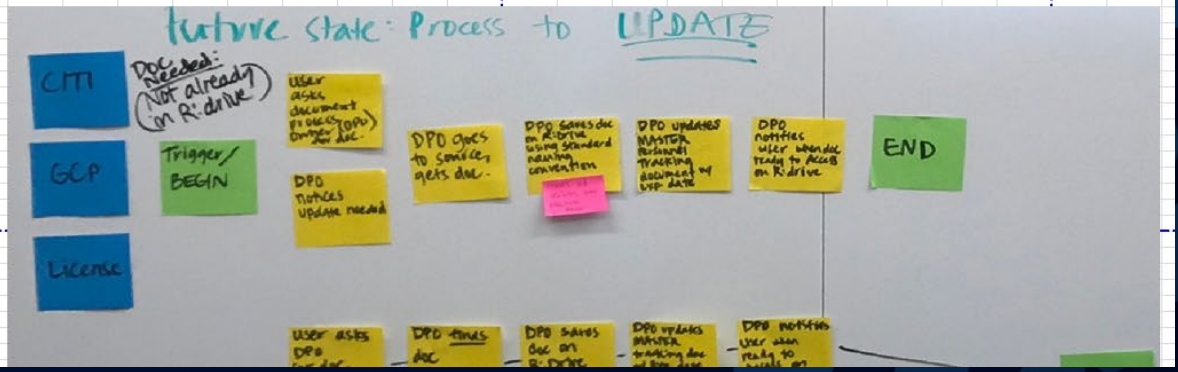
E-Binder Project

Current State:

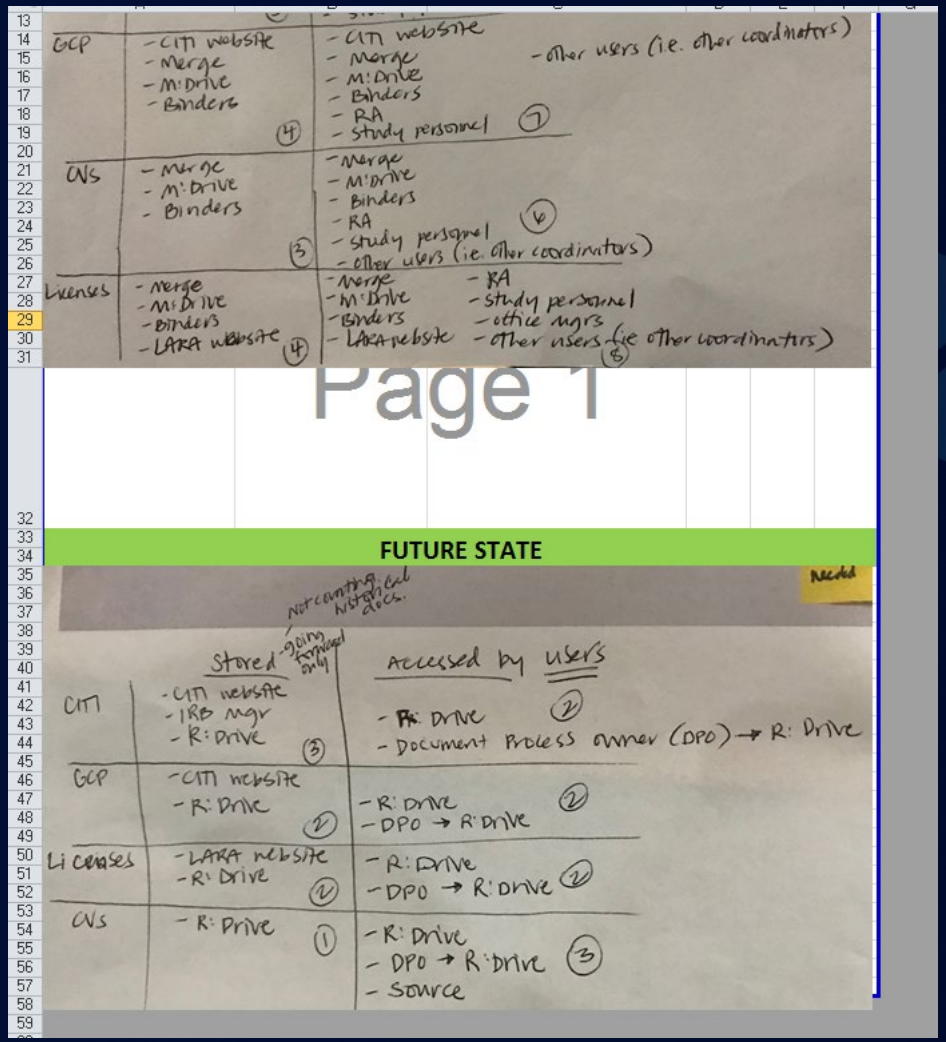


Future State:





E-Binder Project



GCP	- CITI website - Merge - M: Drive - Binders (4)	- CITI website - Merge - M: Drive - Binders - RA - study personnel (7) - other users (i.e. other coordinators)
CVs	- Merge - M: Drive - Binders (3)	- Merge - M: Drive - Binders - RA - study personnel - other users (i.e. other coordinators) (6)
Licenses	- Merge - M: Drive - Binders - LARA website (4)	- Merge - M: Drive - Binders - LARA website - RA - study personnel - office mgrs - other users (ie other coordinators) (8)

Page 1

FUTURE STATE

Needed

Not counting historical docs.

	Stored - going forward only	Accessed by users
CITI	- CITI website - IRB Mgr - R: Drive (3)	- R: Drive (2) - Document Process owner (DPO) → R: Drive
GCP	- CITI website - R: Drive (2)	- R: Drive - DPO → R: Drive (2)
Licenses	- LARA website - R: Drive (2)	- R: Drive - DPO → R: Drive (2)
CVs	- R: Drive (1)	- R: Drive - DPO → R: Drive (3) - Source

Lessons Being Learned

Getting ready to go On Deck is taking a lot longer post conception than expected

Planning stage is usually longer than 3 weeks

Hardest part of doing boxes 1-3 is deciding on metrics

Planning teams tend to jump to solutions before going though PDSA

Gate keeping and maintaining accountability must be maintained – the infrastructure for this is non-trivial

The impact on culture is (anectodally) higher than anticipated

SPECTRUM HEALTH

What Does RiHub Mean to Stakeholders?

SPECTRUM HEALTH

Thanks to the RiHub Planning Committee

Emily Beltz – **Perpetual process planner**, Coordinator II & Team Lead, Pediatrics

Nick Duesbery - **Master Juggler**, Director - Sci Support; WRML (bench lab)

Cat Lucas - **Superstar IRB Analyst** – Senior AnalystResearch Oversight

Benjamin Mundt – **Insightful and Steady Handed**, Manager - All of Us

Derek Nedveck - **Wicked Smart**, Epidemiologist - Scientific Support Services

Ashley Sanchez - **Immensely Helpful**, SH system PI specialist

Julie Talarek - **Truly Dedicated**, Manager, Adult Clin. Ops

Tom Warnshuis - **Steadfastly Reasonable**, Dir., Research Finance and Sponsored Programs.

……Shanta Layton , Chair - **Luckiest Ever, Director - Pediatrics**