Regeneron Discovery Workshop Summary

March 31, 2017

Presented by Twin Technologies
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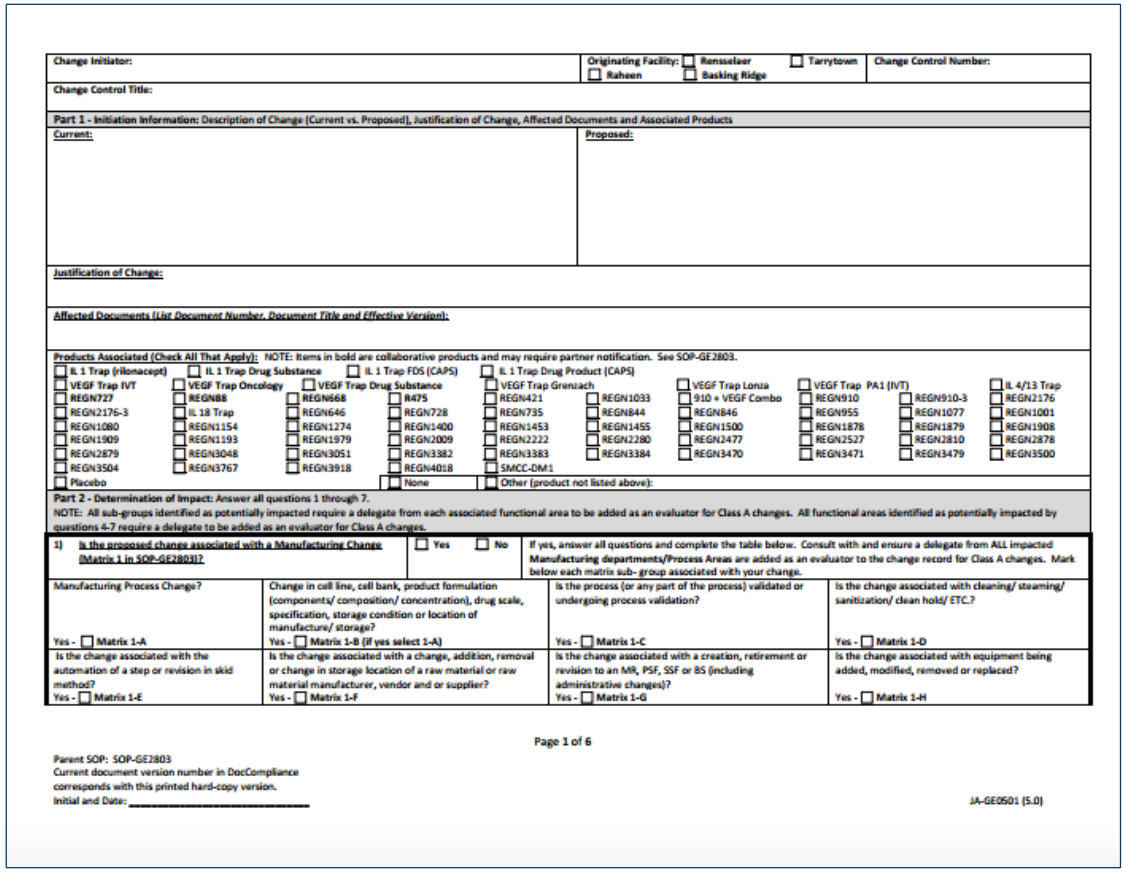
The Challenge

How do you reinvent change control?

The change control process at Regeneron, while owned by QA, crosses almost every major division in the organization. This is a tremendous responsibility. QA has the opportunity to reinvent the change control process, from beginning to end, to accelerate the pace of the business while increasing user satisfaction.

With an opportunity this dynamic and mission critical, how should Regeneron define the short term project while keeping these efforts in alignment with longer term strategic objectives?

Regeneron and Twin engaged in a **two-day discovery workshop** to understand this question. Twin sought to better understand the existing Change Control Process, with an eye to the future, through the use of **design thinking** techniques to look for ways to accelerate value delivery.


Change Initiator:
Originating Facility: Rensselaer Tarrytown Raheen Basking Ridge
Change Control Number:
Change Control Title:
Part 1 - Initiation Information: Description of Change (Current vs. Proposed), Justification of Change, Affected Documents and Associated Products
Current:
Proposed:
Justification of Change:
Affected Documents (List Document Number, Document Title and Effective Version):
Products Associated (Check All That Apply): NOTE: Items in bold are collaborative products and may require partner notification. See SOP-GE2803.
IL 1 Trap (rilonacept) IL 1 Trap Drug Substance IL 1 Trap FDS (CAPS) IL 1 Trap Drug Product (CAPS)
VEGF Trap IVT VEGF Trap Oncology VEGF Trap Drug Substance VEGF Trap Grenzach VEGF Trap Lonza VEGF Trap PA1 (IVT) IL 4/13 Trap
REGN727 REGN88 REGN668 R475 REGN421 REGN1033 910 + VEGF Combo REGN910 REGN910-3 REGN2176
REGN2176-3 IL 18 Trap REGN646 REGN728 REGN735 REGN844 REGN846 REGN955 REGN1077 REGN1001
REGN1080 REGN1154 REGN1274 REGN1400 REGN1453 REGN1455 REGN1500 REGN1878 REGN1879 REGN1908
REGN1909 REGN1193 REGN1979 REGN2009 REGN2222 REGN2280 REGN2477 REGN2527 REGN2810 REGN2878
REGN2879 REGN3048 REGN3051 REGN3382 REGN3383 REGN3384 REGN3470 REGN3471 REGN3479 REGN3500
REGN3504 REGN3767 REGN3918 REGN4018 SMCC-DM1
Placebo None Other (product not listed above):
Part 2 - Determination of Impact: Answer all questions 1 through 7.
NOTE: All sub-groups identified as potentially impacted require a delegate from each associated functional area to be added as an evaluator for Class A changes. All functional areas identified as potentially impacted by questions 4-7 require a delegate to be added as an evaluator for Class A changes.
1) Is the proposed change associated with a Manufacturing Change (Matrix 1 in SOP-GE2803)? Yes No
If yes, answer all questions and complete the table below. Consult with and ensure a delegate from ALL impacted Manufacturing departments/Process Areas are added as an evaluator to the change record for Class A changes. Mark below each matrix sub- group associated with your change.
Manufacturing Process Change? Yes - Matrix 1-A
Change in cell line, cell bank, product formulation (components/ composition/ concentration), drug scale, specification, storage condition or location of manufacture/ storage? Yes - Matrix 1-B (if yes select 1-A)
Is the process (or any part of the process) validated or undergoing process validation? Yes - Matrix 1-C
Is the change associated with cleaning/ steaming/ sanitization/ clean hold/ ETC.? Yes - Matrix 1-D
Is the change associated with the automation of a step or revision in skid method? Yes - Matrix 1-E
Is the change associated with a change, addition, removal or change in storage location of a raw material or raw material manufacturer, vendor and or supplier? Yes - Matrix 1-F
Is the change associated with a creation, retirement or revision to an MR, PSF, SSF or BS (including administrative changes)? Yes - Matrix 1-G
Is the change associated with equipment being added, modified, removed or replaced? Yes - Matrix 1-H
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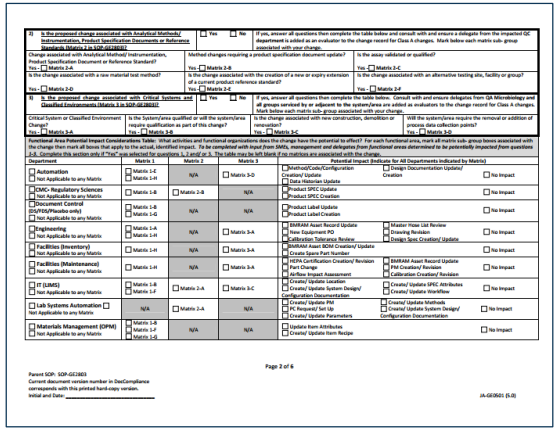
Parent SOP: SOP-GE2803
Current document version number in DocCompliance corresponds with this printed hard-copy version.
Initial and Date: _____
JA-GE0501 (5.0)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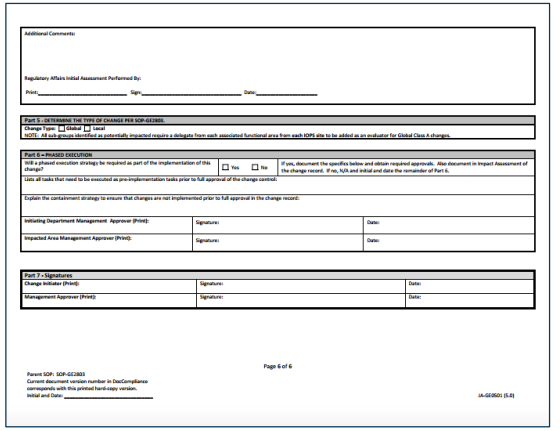
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Process: Collaborative Play

Using empathy and science to understand requirements

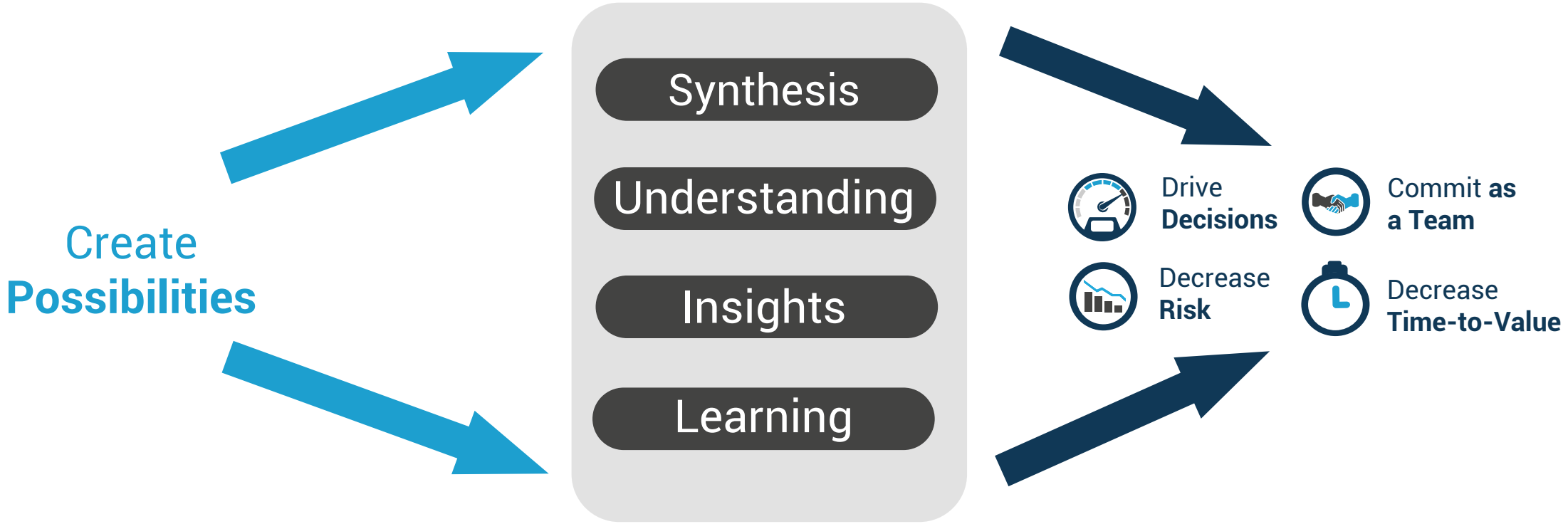
Twin led the team through a number of exercises. Some of these exercises we conducted using white boarding and discussion techniques.

Others were **collaborative innovation games**, designed to explore and creatively uncover features, pain points, dependencies, and success criteria of Regeneron's strategy.

This focused on **generating** a number of **ideas** that were then sorted by impact and priority.

Discovery Process: Design Thinking

Successfully managing innovation requires a framework that fosters creativity and learning. Twin uses divergent and convergent thinking to identify novel solutions to meaningful problems.



Divergent Thinking

Divergent Thinking focuses on creating many possible solutions in a short amount of time. Unexpected connections are encouraged. The focus is not on finding the "correct" solution.

Convergent Thinking

Convergent Thinking focuses on filtering and prioritizing ideas quickly. The prioritization and filtering criteria are unique to each organization's needs.

Workshop Agenda

Day 1: March 16, 2017

1. Introductions and workshop goals
2. Change Control Meeting
3. Business Process Mapping
4. Remembering the future
5. Personas
6. Dinosaur Steps

Day 2: March 17, 2017

1. Dinosaur Steps (continued)
2. Speedboat
3. Brainstorming and Idea Generation
4. Business Requirements
5. Prioritization – Dot Voting
6. Recap and Next Steps

Who attended the workshop?

Regeneron

- Mike Revai – Director, Quality Systems
- Tara Bee – Associate Manager Quality Assurance
- Jennifer Hayes – Sr. Quality Compliance Specialist
- Heather Johnson – Quality Assurance
- Brad North – Associate Manager Product Specifications
- Michael Van Etten – Lead Biotech Production
- Sean Breeze – Lead Sr. Biotech Production Compliance
- Zachary Paul – Engineering Project Manager
- Steve Heilman – Manager Qumas System

Twin Technologies

- George Jagodzinski – Executive Sponsor
- Steve Adams – Engagement Manager
- Benjamin Speaks – Business Experience Designer (Workshop Facilitator)
- Jeremy Messenger – Technical Lead
- Ben Elmore – CEO/Founder

Activities and Exercises

Activity:
Change Control Meeting

Contextual Research and Observation

Activity Description:

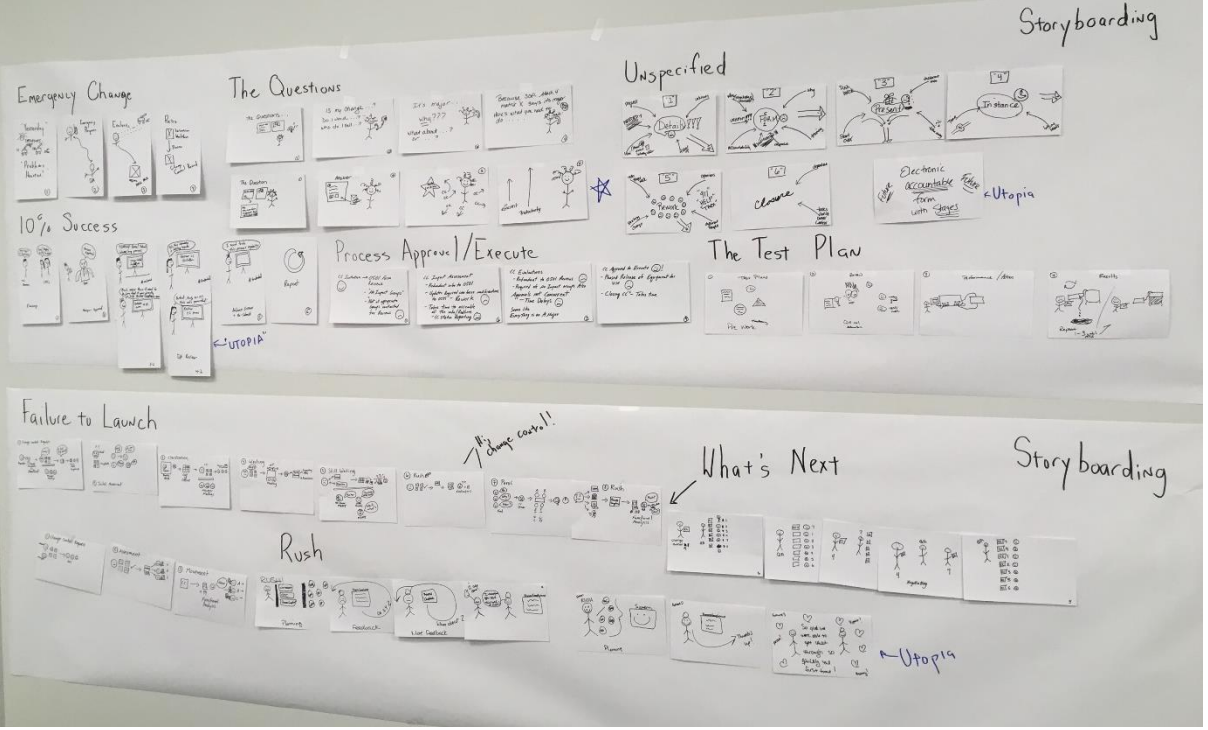
Twin Technologies was invited by QA to observe an actual Change Control Committee (CCC) meeting.

This meeting helped the team understand the stakeholders and complexity of the change control process. While observing the interactions we realized the sheer number of individuals (and departments) involved in assessing a “Class A Major" change control request.

This meeting also gave us a different view into how the Change Control Initiation Form, and its manually populated CCC presentation counterpart, are used in this process.

Key Observations and Themes:

- Highly manual process
- Numerous individuals and departments involved
- Large variation in the experience level of Change Owners
- Extensive coordination required between QA and Change Owners



Activity:
Business Process Mapping

Letting Users Storyboard Their Narrative

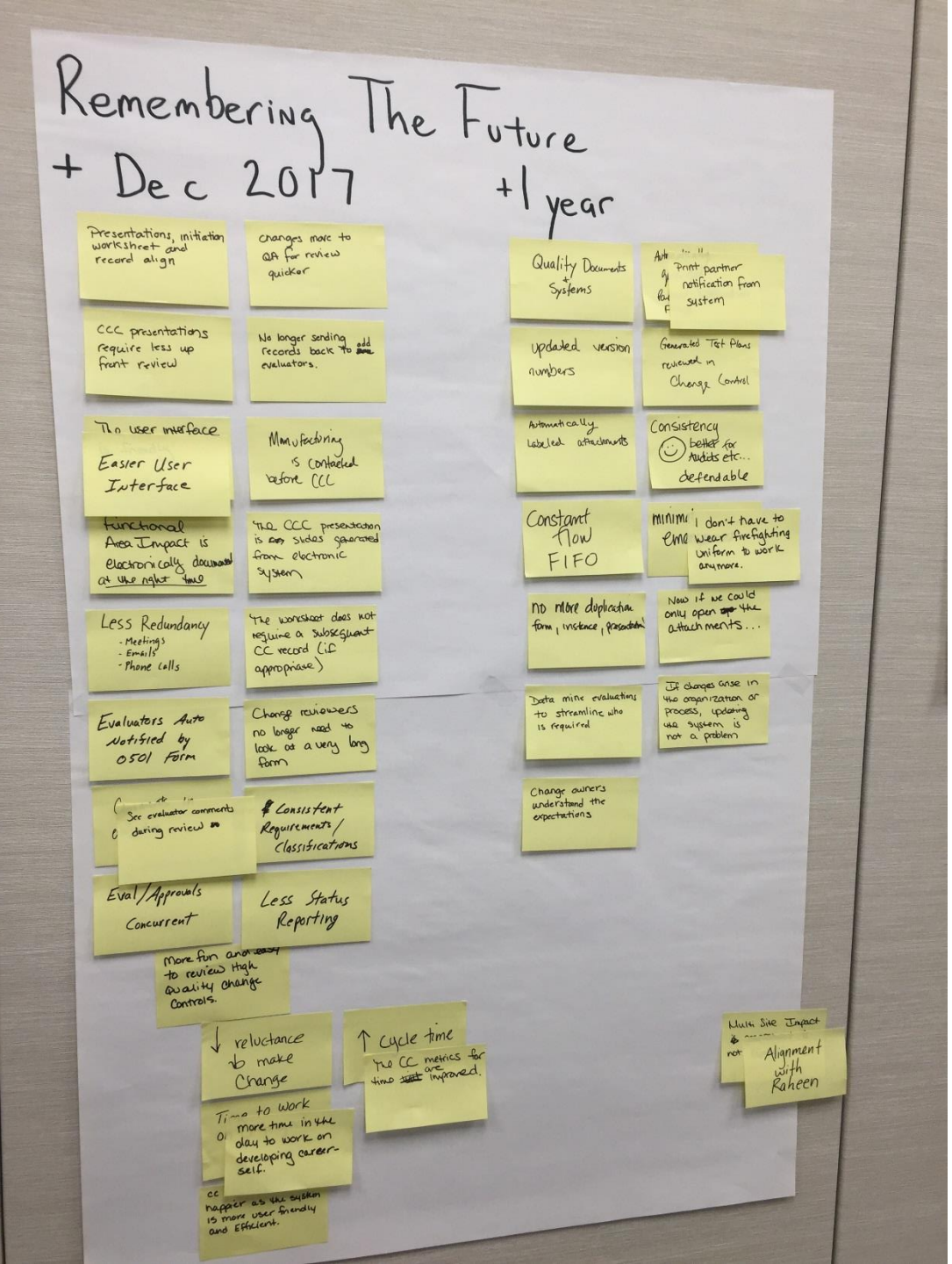
Activity Description:

Each participant was asked, using 4 to 8 notecards, to illustrate a business process from start to finish. Participants were given considerable latitude in choosing their story.

As participants presented their stories, we started to identify common themes of relevance related to their experiences within the change control process. Of equal importance, many of the participants expressed strong emotions regarding their experiences. This created a feeling of empathy between participants in the room. As people began to "loosen up" they became more passionate in their communications.

Key Observations and Themes:

- A need for automation in the process
- Considerable redundancy as related to data entry
- Limited training on the Change Control Process
- A need for features that improve workflow management
- Reactive state to address changing business priorities



Activity: Remembering the Future

Defining Success

Activity Description:

By asking two questions, “If redesigned, what will our product have done in December of this year?” and “If matured, what will our product have done in December of 2018?” By asking these questions, we began to understand Regeneron’s **definition of success** by seeing how they perceive the impact of their product.

Key Observations and Themes: December 2017

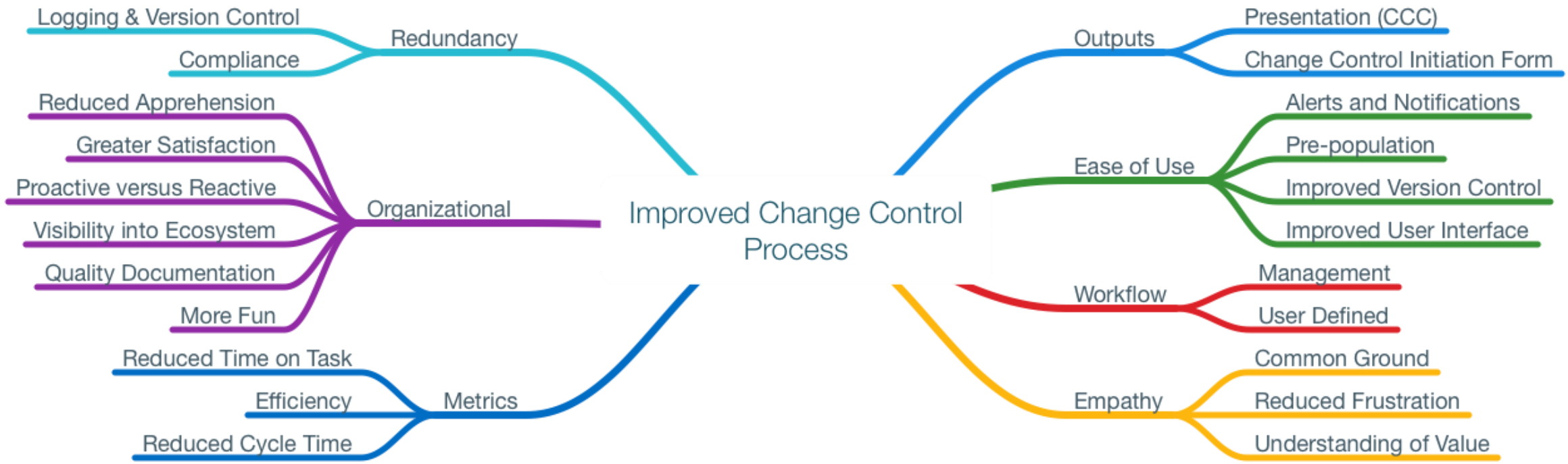
- Enhanced user interface
- Less redundancy
- Auto notifications
- Auto creation of artifacts

Key Observations and Themes: December 2018

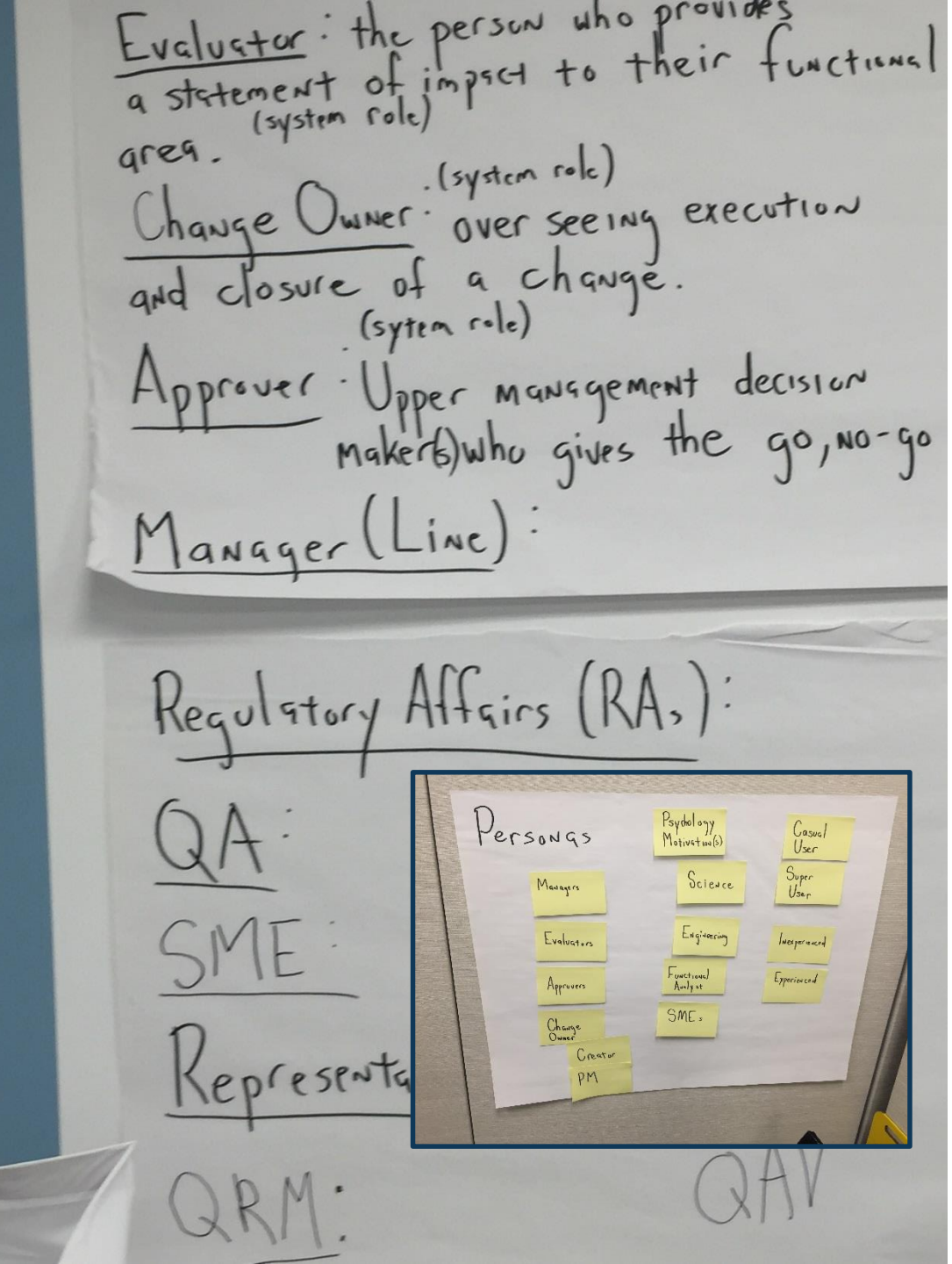
- Constant flow (FIFO)
- Change owners understand QA expectations
- Consistency across all inputs to the process
- Minimize the number of fires QA is addressing

Visualization

Remembering the Future



Synthesis of activity data from onsite workshop.



Activity: Personas

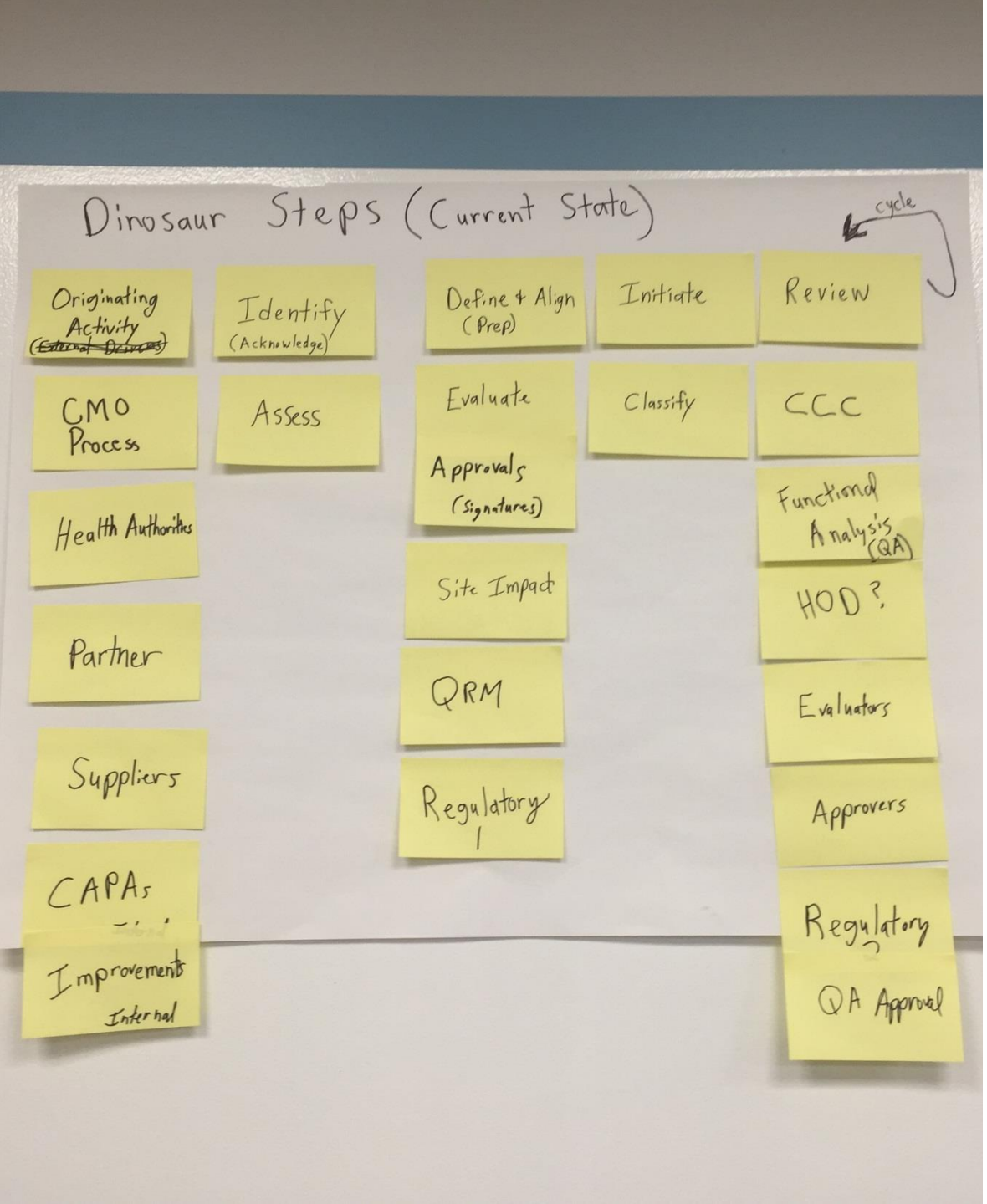
A closer look at the stakeholders

Activity Description:

We listed out the major stakeholders in the Change Control Initiation Process. We then summarized what each persona was responsible for along with their relative place in the chain of command. This gave us empathy into their role and a window into their mindset, objectives and responsibilities.

Key Observations and Themes:

- System roles are specific to the change control process
- System roles are taught using an informal process
- System roles are ad-hoc roles with additional responsibilities
- The workflow between roles is relatively straight forward, but issues sometime arise when selecting Evaluators



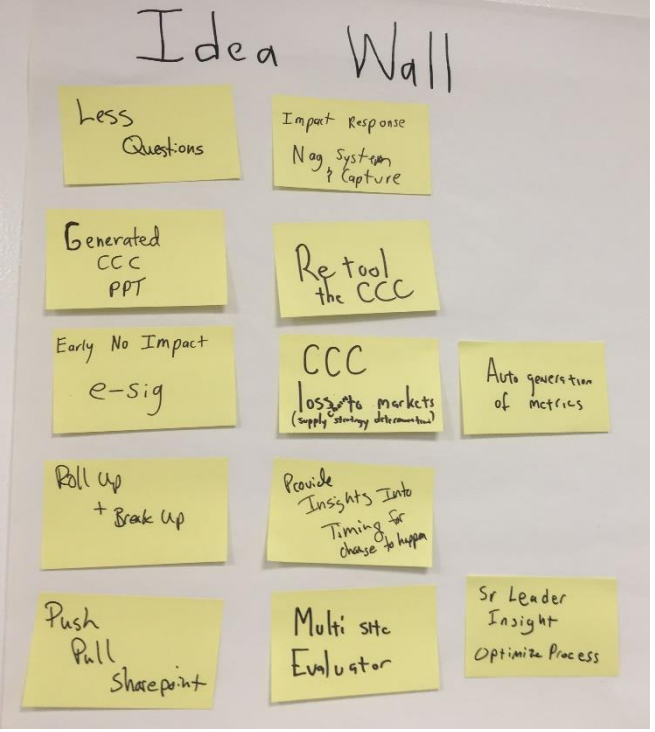
Activity: Dinosaur Steps

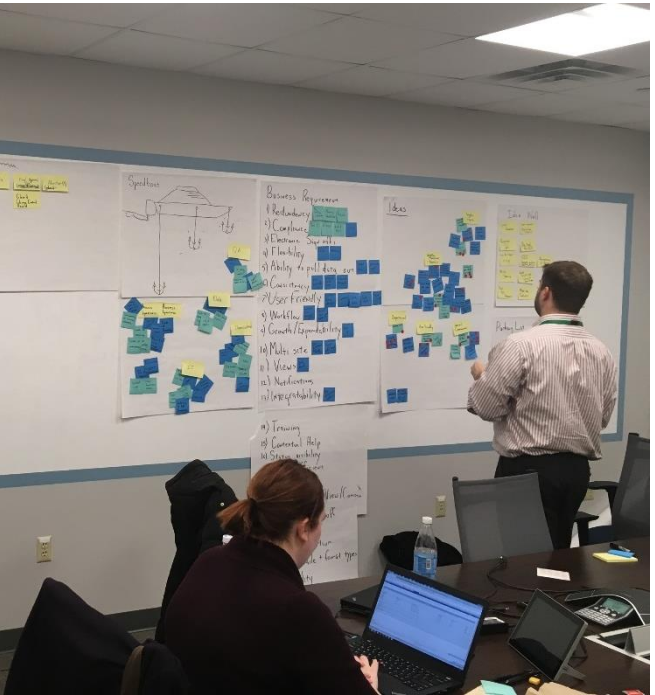
Segmenting the process into manageable phases

Activity Description: We listed all the major phases (dinosaur steps) in the change control process. This validated our understanding of the workflow and gave us insights into how the Change Control Initiation Form is used in the larger change control process.

Key Observations and Themes:

- Minor change controls follow a simplified approval process
- Major change control require a significantly more complex approval process with a presentation to the CCC
- Roles and responsibilities of other internal "compliance" organizations (e.g. QRM, Regulatory Affairs)
- Originating activities (internal and external) that drive change controls within Regeneron (e.g. Supply Chain)





Activity: Whiteboard + Brainstorm

Affinity Diagramming

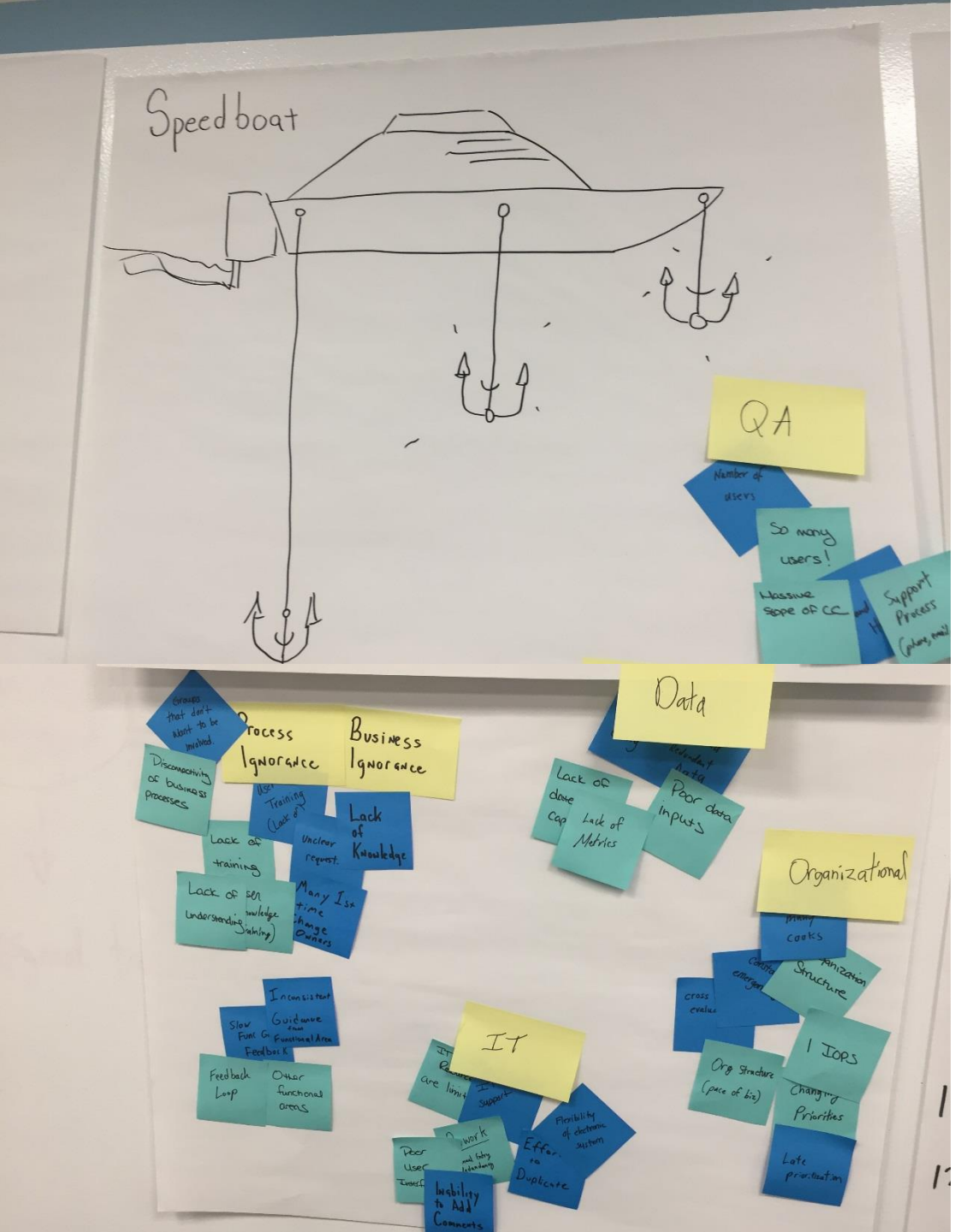
Activity Description:

Ideas generated during the workshop were placed on the Idea Wall.

As the ideas accumulated, we were able to arrange the ideas into **affinity groupings** and identify overarching themes.

Key Observations and Themes:

- Integration with existing internal platforms
- Automatic generation of documentation and artifacts
- Improved e-signature capabilities
- Considerations of Multi-site issues
- Improve metrics and reporting



Activity: Speedboat

A different way to visualize blockers

Activity Description:

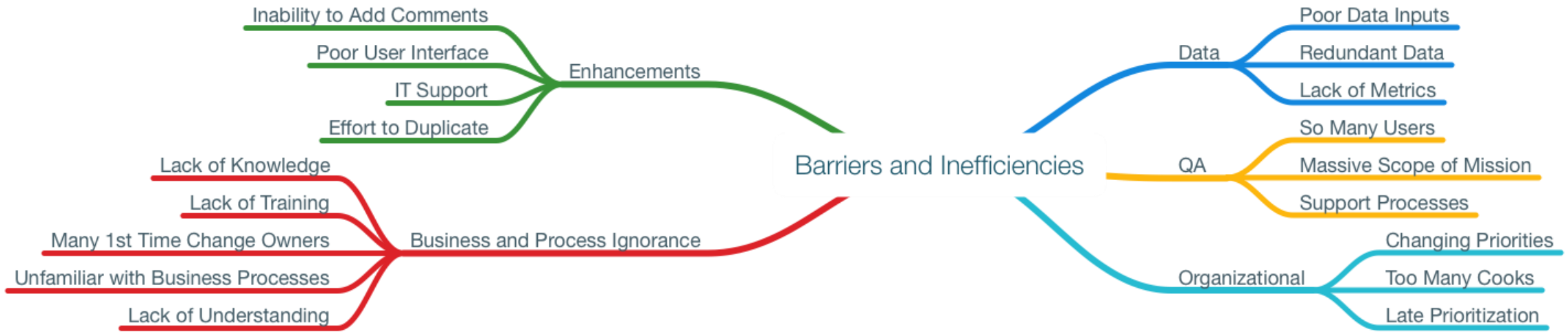
Identify Regeneron's **biggest pain points** by visualizing Regeneron's Change Control Process as a speed boat and its pain points as an anchor slowing the boat down. As each user presented a pain point we discussed the context to gain a better understanding of its impact. This lead into a natural discussion on how we could remove or minimize such anchors.

Key Observations and Themes:

- Stakeholders believe that there are a number of misconceptions about the value and function of QA. A desired outcome is that perceptions towards QA will improve overtime
- There are significant resourcing constraints that impact the ability for the business to move quickly
- Improved user experience could directly address many of the anchors currently slowing the pace of the business
- Vision across the business would benefit from improved reporting and metrics

Visualization

Speedboat Pain Points



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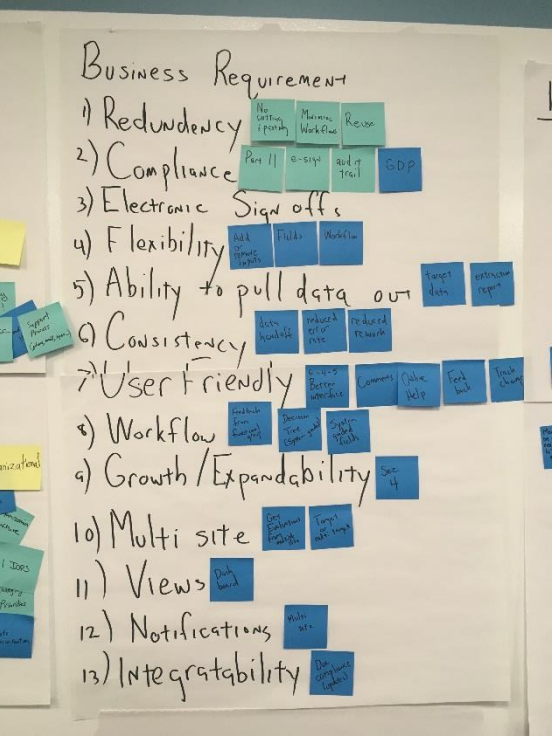
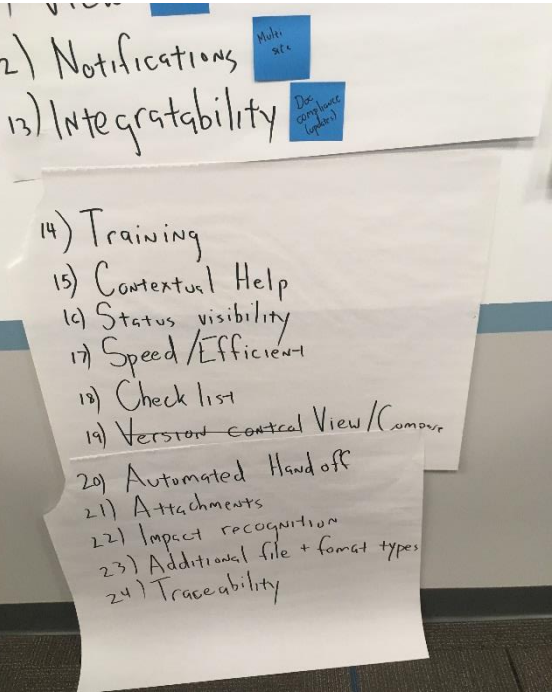




Activity: Business Requirements

Using “speed dating” to rapidly generate requirements

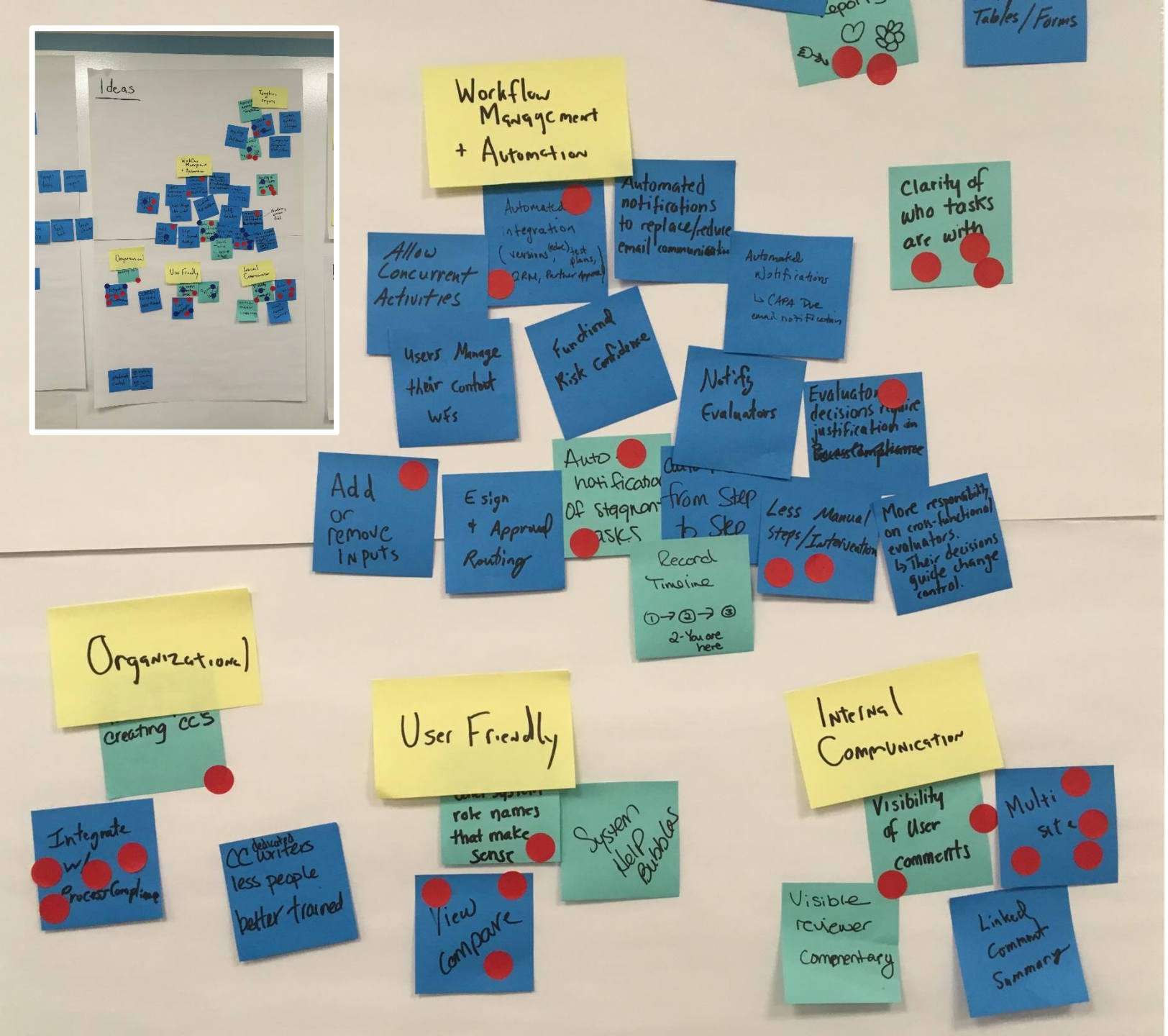
Activity Description:

Using a round-robin format, we rapidly went around the table asking participants to contribute a business requirement. We used this format to ensure participants had an equal voice.

Each participant then described their business requirement in detail to the group, which lead to more in-depth conversation.

Key observations:

- Significant alignment existed between the earlier exercises (Speedboat, Remember the Future) and Business Requirements
- Workflow Automation and Ease of Use were identified as critical to the success of the project



Activity: Prioritization

Affinity Diagramming + Dot Voting

Activity Description:

By giving each Regeneron stakeholder a limited number of votes, we narrowed down our ideas to what we believed were the highest priority. We discussed the magnitude of the impact and which would generate the most value. Afterwards, we linked similar ideas.

Key Observations and Themes:

- Voting validated team alignment on prioritization of key requirements / features
- Workflow Automation and Usability is critical to all stakeholders.

Outcomes...

Outcomes | Needs

Pragmatically, the initial solution will need to:

- Minimize redundant data entry
- Automate key system interactions and integration points (i.e. ProcessCompliance)
- Enhance workflow, notification, and management features
- Provide a seamless interface and user experience
- Extend reporting on events and users in the QA ecosystem
- Reduce time spent on onboarding and support tasks

Outcomes | Themes: EASE OF USE

As the business has evolved, the change control process and tools have grown organically—becoming more complex, time consuming, error prone, and generally overwhelming to navigate. The change control initiation process suffers from a high 'first time right' failure rate due to its complexity and its unfamiliarity to the users.

Business Impact

1. **Organizational Friction**: Added friction to the overall change control process and its desired outcomes
2. **Support**: Extensive onboarding and support required, contributing to a "constant state of rush"
3. **Cycle Times**: Increased cycle times and slower "time-to-market" for changes
4. **Operational inefficiencies**: increased time-on-task

Opportunities (Future State)

Gain efficiencies and accelerate the pace of business by providing a user-friendly interface and streamlined user experience. Enabling the ideal experience will extend well beyond the user interface (e.g. automation of key system interactions and integration points, flexible workflow, etc.)

Outcomes | Themes: DUPLICATION & ALIGNMENT

Several change consultation organizations currently exist within Regeneron (e.g. CC, QRM, RA). These organizations have their own best practices regarding change control processes. The result is lack of a holistic view of the change request and a duplication of efforts by change owners.

Business Impact

- Increased cycle times and slower “time-to-market” for changes
- Added friction to the overall change control process and its desired outcomes
- Stakeholder satisfaction (QA viewed as an obstacle)

Opportunities (Future State)
Automation of the change control initiation form is the immediate goal, follow up conversations with the QRM would prove beneficial to reduce duplication of efforts and improve operational efficiency.

This gap creates an opportunity to enhance reporting and communication between these entities.

Outcomes | Themes: REPORTING

Senior leaders lack visibility into metrics which could provide a more holistic view of change control across the organization. Additionally, the QA group currently relies heavily on manual efforts to pull together key reports for the business.

Business Impact

- Lack of visibility to inputs across the entire Quality Control ecosystem (e.g. Supply Chain Compliance Group)
- Operational Inefficiencies (e.g. RTO)
- Inability to easily and accurately report Change Control metrics and outcomes in real-time

Opportunities (Future State)
Identify quick ways to solve the biggest reporting pain points before attempting a “big bang” approach with a large scale Business Intelligence (BI) solution. Enhanced reporting and dashboards, would improve operational efficiencies, provide additional metrics to the business, and more importantly, provide topsight to the change control process.

Pragmatically, data mining should be considered to more effectively identify evaluators, recognize bottlenecks early in the process, and ultimately drive business optimizations.

Outcomes | Themes: ORIGINATING ACTIVITIES VISIBILITY

As change control has evolved, the lines delineating the processes, process owners, and artifacts have become blurred. Change controls that originate from external sources (e.g. CMOs, Partners, Suppliers, etc.) are often outside the purview of the QA organization as they are channeled through the Supply Chain Compliance Group.

Business Impact

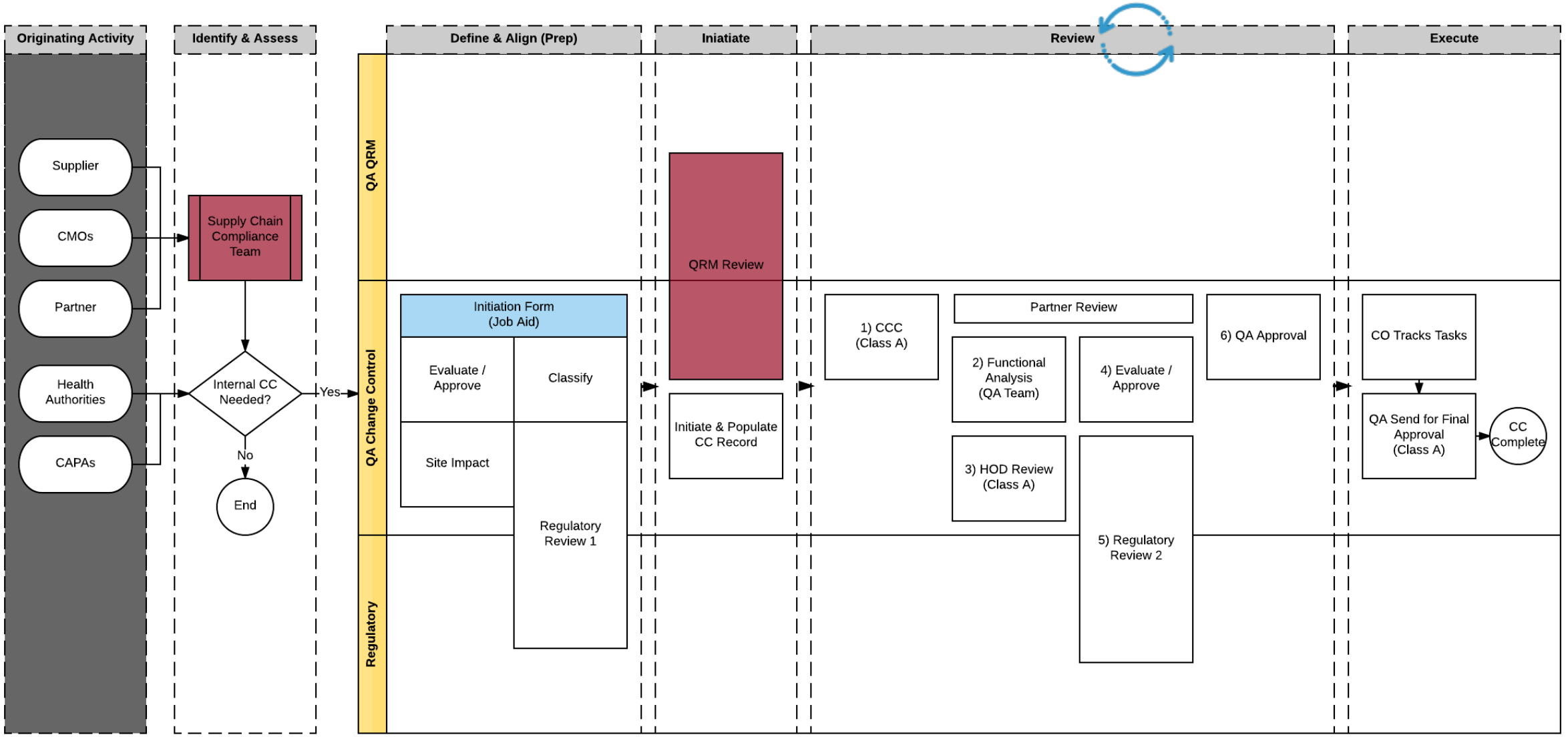
Supply Chain: Lack of visibility into supply chain creates the potential for a cascading effect when production changes are bottlenecked by process. In this worse case scenario, this could result in a missed window of opportunity/revenue around a specific campaign.

Opportunities (Future State)
Changes within the ecosystem are naturally going to impact other groups across the organization and their strategy. To ensure there are no misses (or near misses), we need to not only enable visibility, but also predictability into the process so the business can adapt quickly as changes are introduced.

Additional discovery is required to determine potential path(s) forward to improve visibility and mitigate organizational risk.

Change Control Ecosystem

Areas that need additional focus and clarification noted in red



Outcomes: Synthesis

Driving Business Agility: Highly Effective Teams

Business agility starts with building effective teams. As the control gate for change within the business, QA is a major factor in the overall business agility at Regeneron. People want to feel good about their work. They want to make a difference, add value, and avoid spinning their wheels on repetitive mundane tasks.

In the current state of QA, the value-to-effort balance is askew. Senior QA resources spend disproportionate hours of their days on support tasks, while change owners view QA as an obstacle to moving the business forward. Individuals inside of QA should apply their hard earned knowledge to difficult problems (and not data entry). Individuals outside of QA should implement change controls processes without feeling uncertain, ignorant, or confused.

Addressing underlying issues with change control initiation will empower users to push straightforward changes (i.e. Class B, C, D) through the change control ecosystem with limited friction. The improved overall experience will in turn allow the teams to:

- Focus efforts on complex issues that truly move the business (e.g. Class A Major changes)
- Reduce friction to the overall change control process while improving business agility
- Realize operational efficiencies → Decreased cycle time → Improved time-to-market

Outcomes: Synthesis

Maximizing Value Through Focused Efforts

The desired end state is a solution that streamlines the entire change control process from end-to-end. The first phase is to focus on the change control initiation process and those systems directly impacted by the initiation step.

Change control initiation ease-of-use, workflow automation, and integration with other key QA systems offer the greatest immediate impact to the business. In the long run, value propositions around increasing ecosystem awareness, reducing cycle time, and alignment with other internal entities needs to be explored in more detail.

Cross Functional Teams: Streamline Process Across All Groups

An opportunity exists to improve organizational alignment with other internal change consulting groups. For example, duplicative processes with other quality consultation groups (e.g. QRM), or limited visibility into external CC inputs (e.g. Supply Chain). These issues drive operational inefficiencies, internal frustrations, and reporting challenges.

Consider creating a cross-functional team (CC, QRM, RA, Supply Chain Compliance, IT) that will stay together as a cohesive unit to help the organization better understand the need and identify additional areas to address to support this future vision.


Dinosaur Steps (Current State)
Speedboat
Business Requirement
1) Redundancy
2) Compliance
3) Electronic Sign offs
4) Flexibility
5) Ability to pull data out
6) Consistency
7) User Friendly
8) Workflow
9) Growth / Expandability
10) Multi site
11) Views
12) Notifications
13) Integratability
Ideas
14) Training
15) Contextual Help
QAV

What's Next?

What's Next?

Based on the workshop results, the discovery engagement team will focus next on:

- User experience and ease-of-use metrics
- Gap analysis of existing and desired state
- Technical discovery as related to infrastructure, development and platform architecture
- Developing a high level project plan (Roadmap)
- Solution definition and alternatives


Twin Technologies
human first.