Research Process Improvement (RPI) Toolkit

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What is Research Process Improvement?

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Research Process Improvement (RPI) focuses on improving efficiencies and processes that are involved in clinical research. RPI utilizes a Quality Improvement (QI) framework and many of the same tools to streamline the way research is conducted.

Q: How can RPI help me as a researcher or research team member?

A: There are many RPI tools, just like in QI, that can assist study teams with overcoming challenges in their research and speed up many of the processes that delay research studies. Examples of challenges may include: challenges with study start-up, participant recruitment, protocol design, and research project management tasks.

Q: How is RPI different from a research study?

A: A research study is often designed to answer only one question and it is the investigator's job to prove or disprove a hypothesis. RPI is an applied science that does not seek to research something novel, but rather aims to optimize the process in the real-world. Its primary goal is to improve the way a research study is conducted.

Q: How is RPI different from QI?

A: RPI is very similar to QI and uses many of the same tools and methodologies. The difference is that RPI is applied to research, whereas QI is traditionally used to improve clinical care and healthcare delivery.

Q: Who is this toolkit designed for?

A: This toolkit is designed for anyone engaged in research. The target audience includes: principal and co-investigators as well as research staff, coordinators, and administrators.

Q: How should I use this toolkit?

A: This toolkit includes the full table of contents organized by sub-categories. You can click on any blue text to bring you straight to the page you are interested in. You can also review the process map on Page 4 to determine where it is your team may be struggling and click on the step to learn more about it and/or to access relevant tools.

Steps of a QI Project

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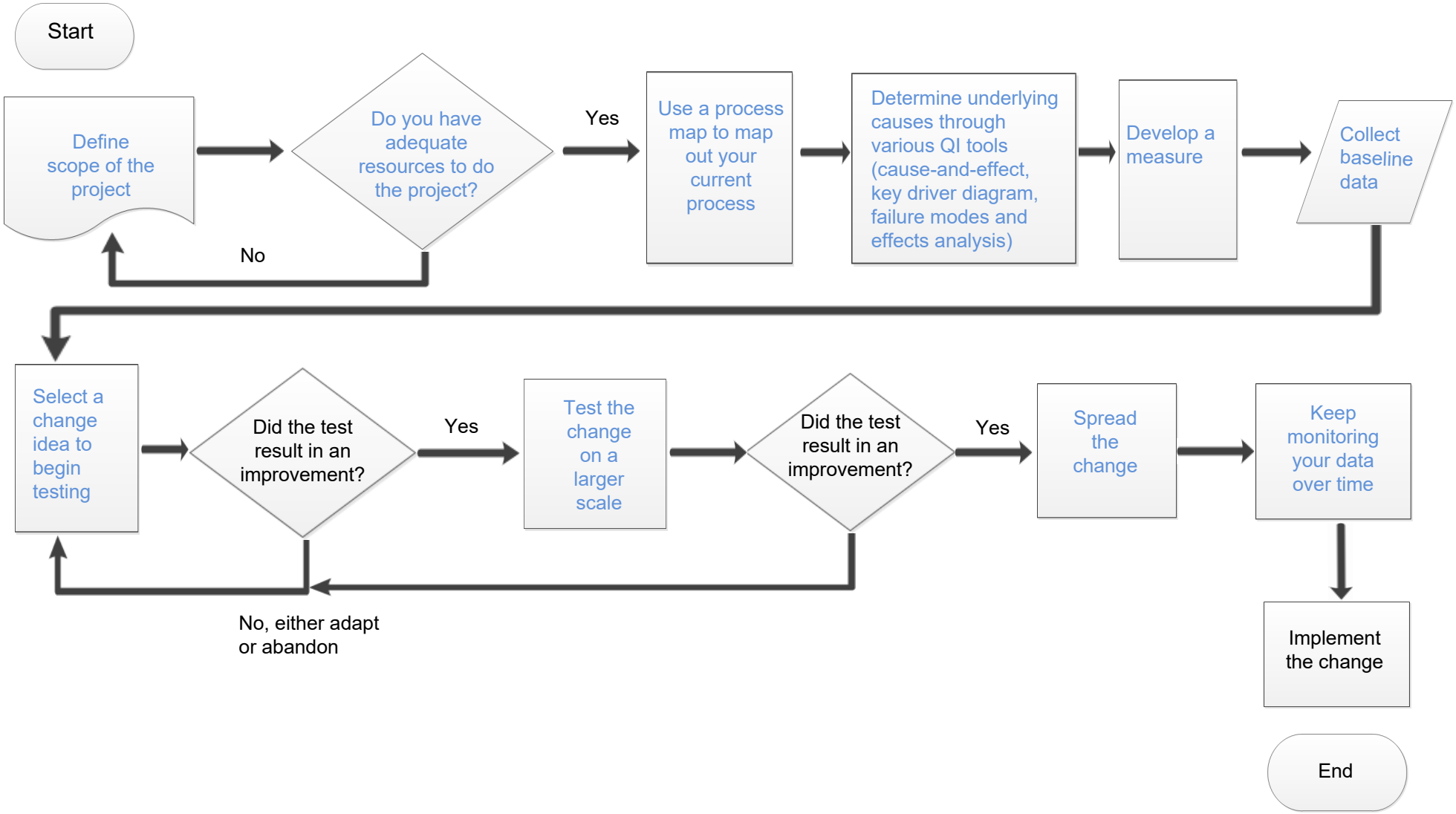

Defining the Scope

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Before embarking on a process improvement project, it is critical to do an assessment to ensure that there is enough time, resources, interest, and need for the project. Strategic planning at the beginning will go a long way in determining its success . During this first step, one needs to answer the following questions:

1) Staff: Do I have enough staff who can dedicate time to this project? If not, can I ask senior leadership for additional support?

2) Stakeholders: Who are the stakeholders in this project? Have I made the identified stakeholders aware of it? Do I have a clear understanding of how my findings will affect them? Have I involved any of the stakeholders in the process change planning?

3) Buy-in: Do I have the stakeholders' buy-in and support for the project? Are they motivated and willing to participate as team members and/or champions in it?

Helpful Tools:

Stakeholder engagement tools and resources- https://www.tuftsctsi.org/research-services/stakeholder-community-engagement/community-engagement-tools-resources/

Problem Statement and Project Plan

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Once the scope of the project has been decided, it is necessary to determine an aim and key objectives. Helpful questions to ask oneself include:

1) Background: Why am I doing this project?
2) Aim: What is my overall goal and what am I hoping to achieve?
3) Objectives: How can my key objectives guide me or my team towards achieving the identified aim?
4) Milestones: What are the most important project activities that I will need to track?
5) Timeline: What is the duration of my project?

Helpful Tools:

Creating **SMART Goals/Objectives**- https://www.smartsheet.com/goal-tracking-setting-templates

Creating **Gantt Charts**- https://asq.org/quality-resources/gantt-chart

Project Plan Template

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Title:	*Add your project title.*
Aim:	*Describe what you are trying to accomplish. Include a timeline and list individuals involved. Make sure your aim is something that is measurable and time-bound.*
Background:	*In four sentences, explain why you are proposing this project.*
Key Objectives:	*Determine key objectives for this project. Make sure they are specific, measurable, achievable, relevant, and time bound, and relate to the overall aim you have listed above.*

Project Plan Worksheet

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Title:	
Aim:	To understand what participants are taking away from the HOPE
Background:	
Key Objectives:	

Process Mapping

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Whenever looking to change a process, it is helpful to map the process out from start to end to understand all the steps involved. It will make it easier to determine where steps can be eliminated or streamlined and identify any steps that can happen in parallel to speed up the project implementation process. It is sometimes helpful to map out the "current state" and also the "ideal state" to assess what changes need to be made to get to the ideal process.

Below is an explanation of different symbols used in the process mapping:

Task or process step

Document

Database

Data

Decision: usually has an arrow leading away with a "yes" and another path for "no"

Indicates the beginning and end of the process

Connects steps and shows the direction of the process

Example Process Map #1

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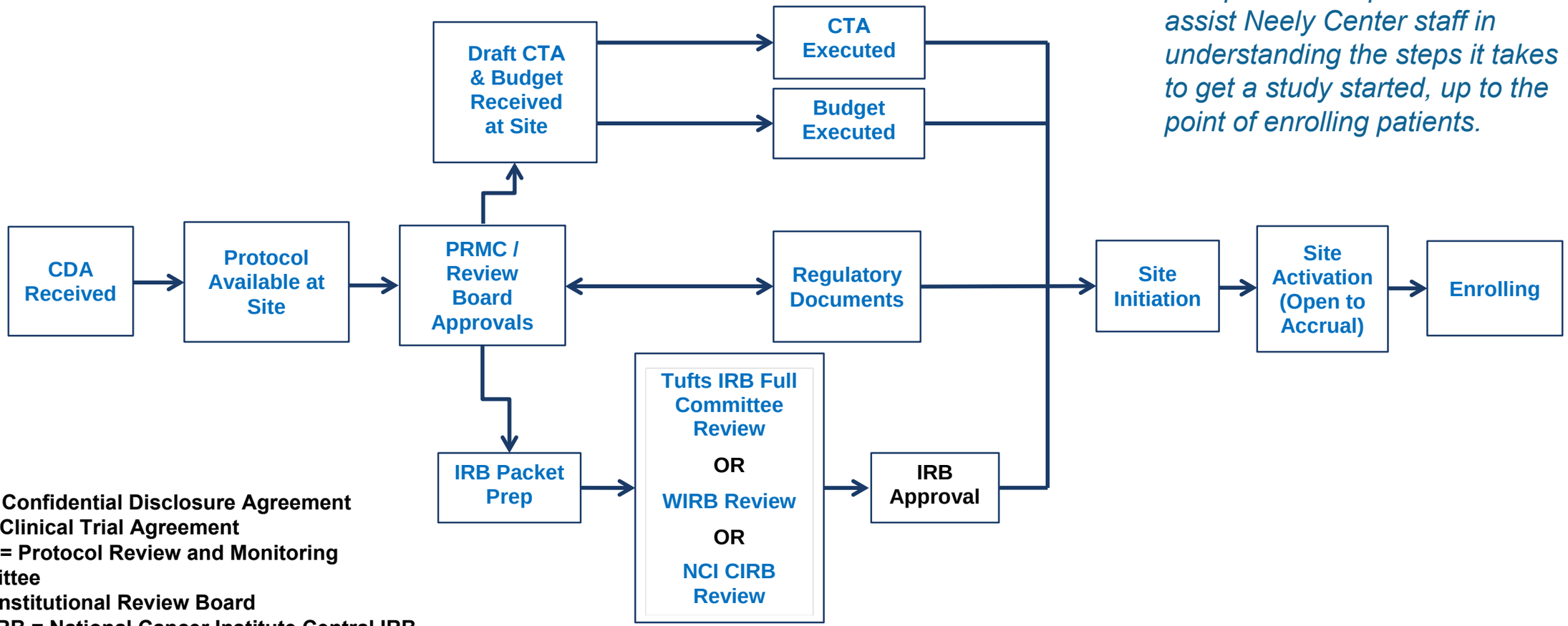
Study Startup Process at the Neely Center for Clinical Cancer Research

This process map was created to assist Neely Center staff in understanding the steps it takes to get a study started, up to the point of enrolling patients.

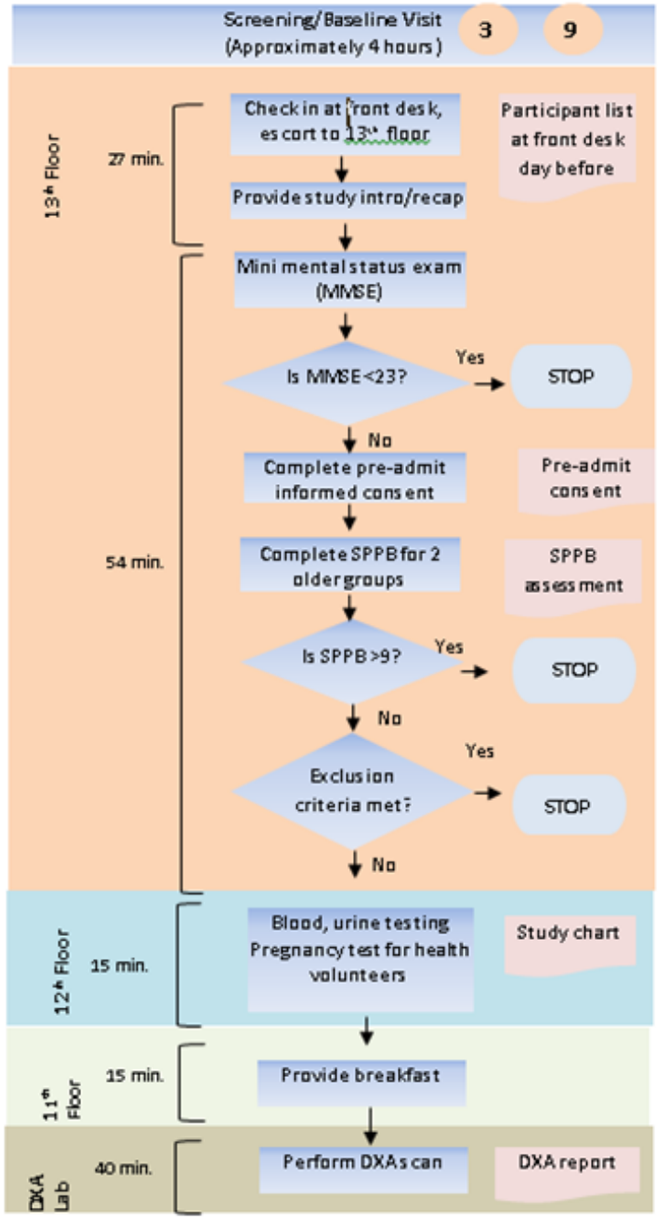


CDA = Confidential Disclosure Agreement
CTA = Clinical Trial Agreement
PRMC = Protocol Review and Monitoring Committee
IRB = Institutional Review Board
NCI CIRB = National Cancer Institute Central IRB
WIRB = Western IRB

Example Process Map #2

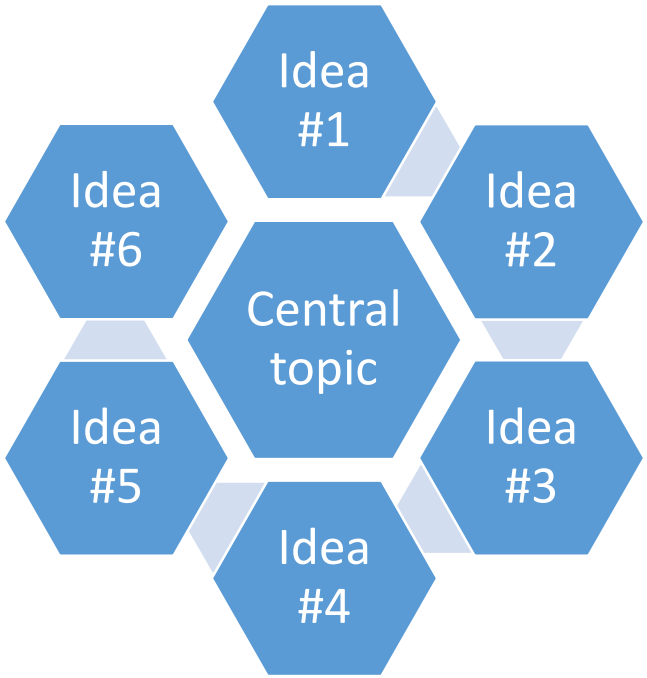
The process map on the right was used to map out the time it would take a study participant to to flow through the visit and complete all the necessary study activities. The team timed each step to see where the visit could be improved to reduce inefficiencies.

Sometimes, it may be helpful to have a mock patient visit to trial out flow issues so that they are resolved before participants get involved in a study.



Brainstorming

The goal of a brainstorm is to put as many ideas down on paper before narrowing them down. All ideas are encouraged in the first round to ensure active participation. There are several ways brainstorming can be facilitated. If there is a concern that a select few will bias or sway the rest of the group, it may be helpful for individual members of the team to generate their own ideas independently before coming together as a group. It may be helpful to have a facilitator selected in advance to help manage the conversation and make sure that everyone is given the opportunity to participate in the brainstorm.



Further Reading

Seven brainstorming techniques for your next ideation session:

https://www.forbes.com/sites/robertbtucker/2017/11/16/seven-brainstorming-techniques-for-your-next-ideation-session/#250096386d5d

Cause-and-Effect Diagram

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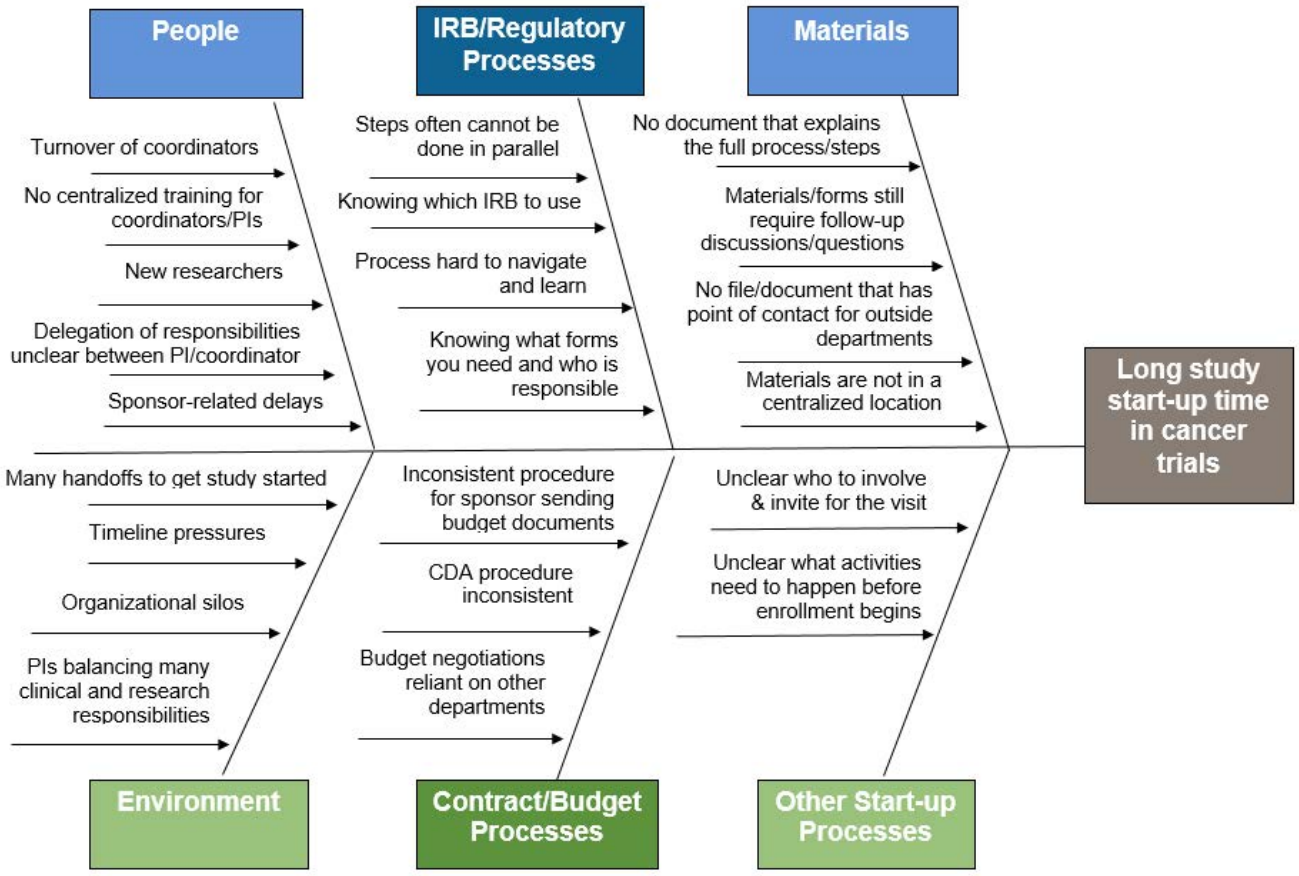
A cause-and-effect diagram is helpful to organize a brainstorm. It is important to identify the problem being addressed and all the contributing factors and underlying causes of it. A cause-and-effect diagram is also often called a “fishbone” diagram because of its structure that looks like a skeleton of a fish.

The diagram allows for grouping ideas by categories of underlying factors. Below are the most common ones that often play a big role:

1) People
2) Materials
3) Processes/procedures
4) Environment
5) Measurement
6) Equipment

Here is an example of a cause-and-effect diagram outlining contributing factors to long study start-up time in cancer trials



Cause-and-Effect Diagram Template

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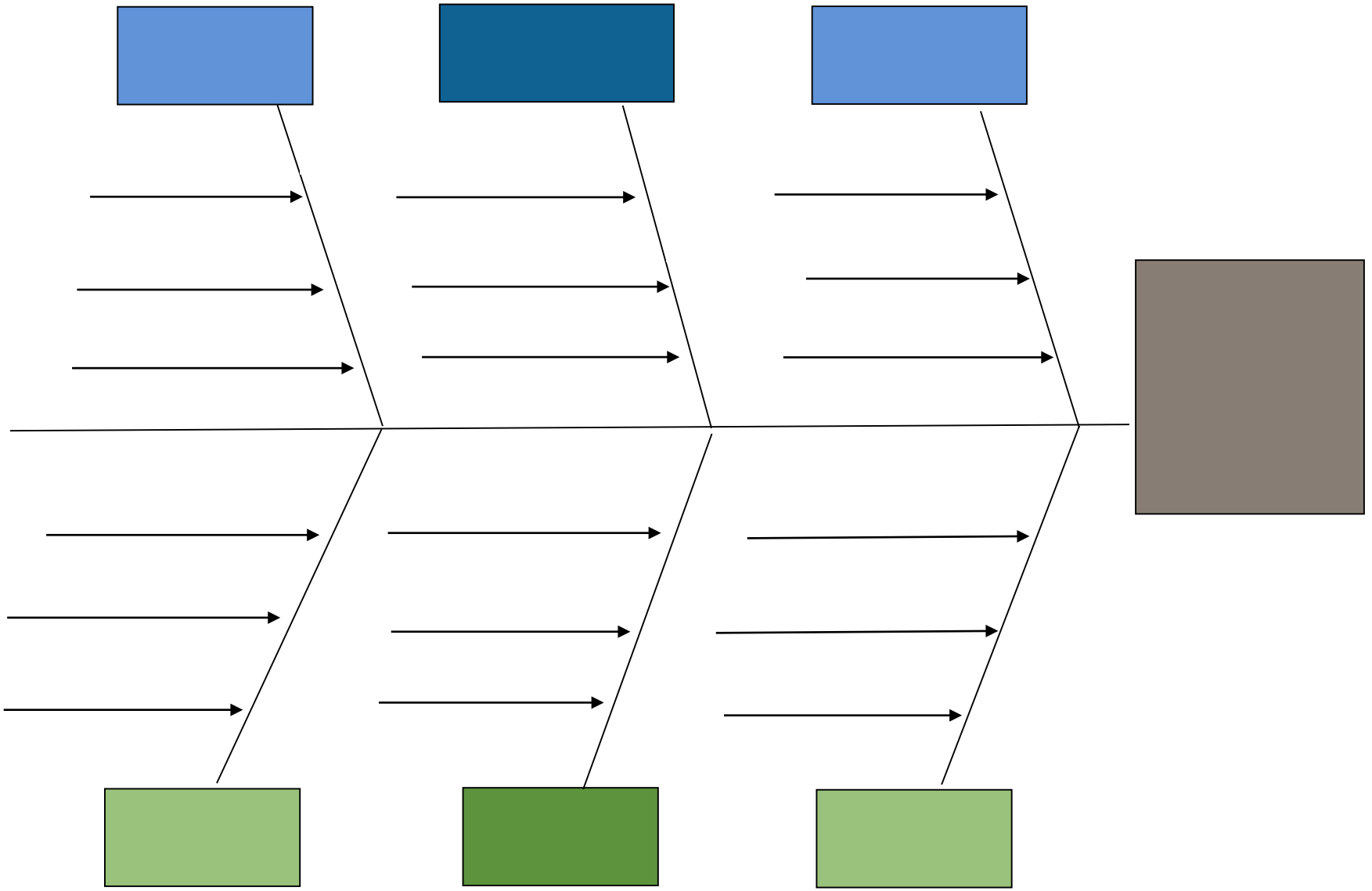

Key Driver Diagram

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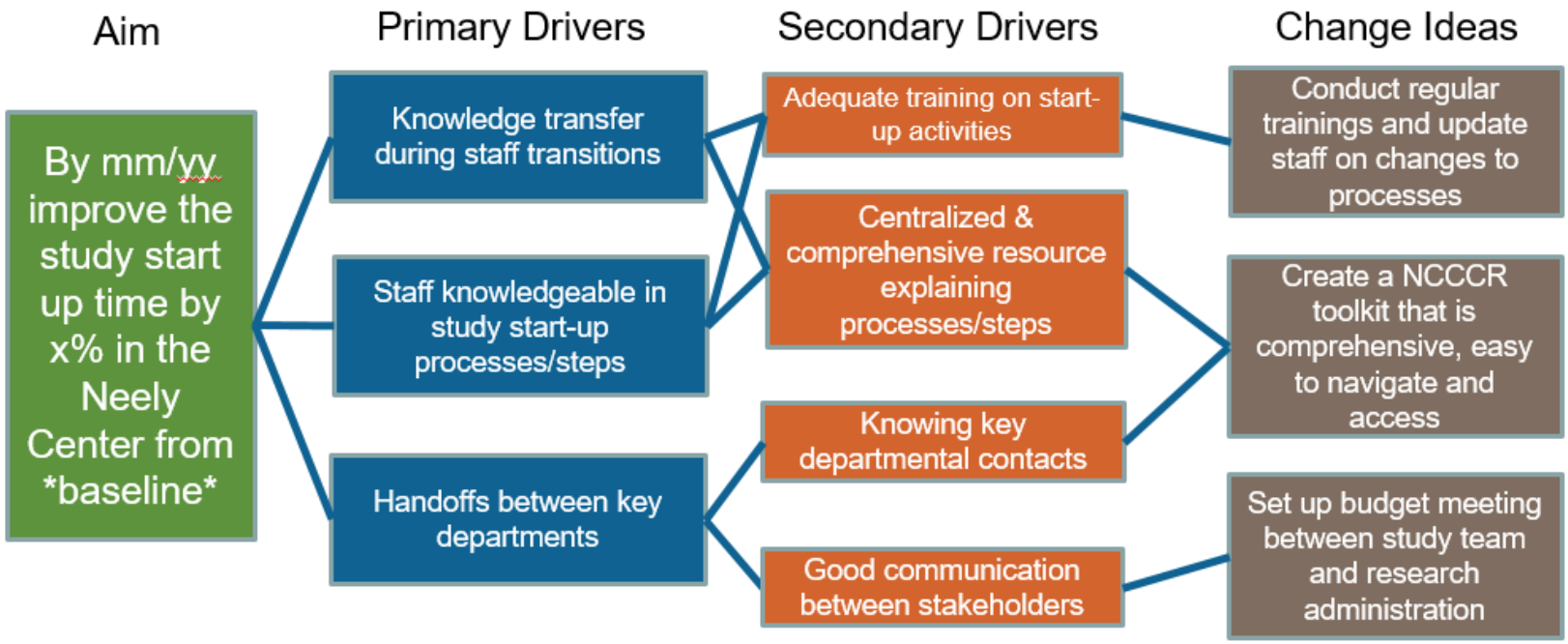
A key driver diagram (KDD) is used to visualize all the drivers that will affect the project's overall aim. It also shows the relationship between primary and secondary drivers. The aim, which is usually listed on the left hand side of the diagram, has the primary and then secondary drivers flowing into it. The diagram also lists any identified change ideas that may impact the drivers. These change ideas are usually listed on the right hand side of the diagram. The drivers should match the underlying causes identified in the cause-and-effect diagram.

Below is an example of the diagram:



Failure Modes and Effects Analysis

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After using a process map to visualize a process from start to finish, a Failure Modes and Effects Analysis (FMEA) can be conducted to assess the vulnerability of that process. An FMEA is a useful tool to see where there are failures and unexpected consequences in a system. It can help a team mitigate these failures and think through solutions for improving the process. In this example, we are using a table from IHI's QI Essentials Toolkit. Here are the steps involved: 1) List out the steps in the process in the first column. 2) Failure mode column: What could go wrong in that step? 3) Failure causes column: What caused those failures? 4) Failure effects column: What is the effect or consequence of that failure? 5) What is the likelihood of that failure occurring? (1= very unlikely and 10= highly likely) 6) What is the likelihood of that failure being detected? (1= very likely and 10= highly unlikely) 7) What is the likelihood that if the failure occurs, it will cause severe harm? (1= very unlikely and 10 = highly likely) 8) Multiply the scores from #5, #6, and #7. The lowest score would be a 1 and the highest would be 1,000. This is the Risk Profile Number (RPN) 9) List possible actions that can reduce the occurrence of the failure listed in each row.

Prioritize improvement work around the steps/processes that have the highest RPNs.

Steps in the Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1-10)	Likelihood of Detection (1-10)	Severity (1-10)	Risk Profile Number (RPN)	Actions to Reduce Occurrence of Failure
1								
2								
3								

Reproduced from IHI's QI Essentials Toolkit

Data Collection

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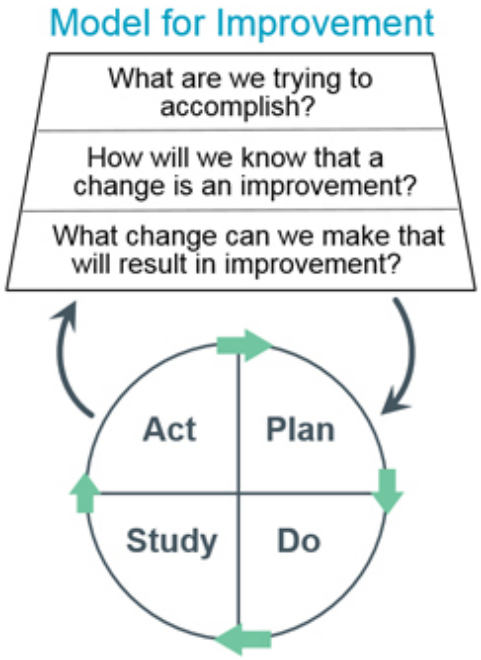
The figure on the right highlights the three key questions under the "Model for Improvement". In order to answer the second question, "How will we know that a change is an improvement?" one needs to set up a way to collect data and compare any progress made against the baseline. To be able to do it, it is important to first determine what is being measured and how it is going to be measured. The **template guide** on the next page can be used to assist with developing a metric.

It is important to have a baseline to know where one is starting from. It is also helpful to have it in order to set an appropriate and realistic goal.

When thinking through the data collection process, it is helpful to answer the following questions first:



Source: Institute for Healthcare Improvement

1) Am I able to easily collect these data?

If collecting the necessary data fields is very time-consuming, it may not be worth the effort. Consider refining your metric so that you are able to get the maximum value.

2) Am I planning to collect data on at least monthly intervals?

If you are only able to collect data on quarterly intervals, it will take a long period of time for your team to be able to "act" on the data. You need higher frequency data intervals, because it takes several data points before you are able to detect a trend.

3) Is the metric I am choosing easy for my team to interpret?

If the metric is not easy to interpret it will be of no use and hard for your team to act on the results.

See the PDSA page for details on how to plan a PDSA cycle.

4) How will I share these data back to the team?

Make sure to keep your team informed on a regular basis. You and your team should decide what interval frequencies make sense.

Operational Guideline Template

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The following template can be used to help develop a metric or measure of interest.

Template Element	Description
1. Metric Title	*Name of metric*
2. Rationale	*An explanation that states why it is important to collect data/information on this measure. This may include specific literature references, evidence based information, expert consensus, etc.*
3. Operational Specification	*Description of metric being measured*
4. Timeframe and frequency	*Timeframe and frequency of data collection*
5. Numerator and Denominator and Inclusion/Exclusion Criteria	*Define what is included in both the numerator and denominator. What cases are included and define who is excluded. Be as explicit as possible.*
6. Data Sources & Methods of Data Collection	*Data sources, method of data collection*
7. Notes/Comments	*Additional notes/comments*

Operational Guideline Worksheet

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The following template can be used to help develop a metric or measure of interest.

Template Element	Description
1. Metric Title	
2. Rationale	
3. Operational Specification	
4. Timeframe and frequency	
5. Numerator and Denominator and Inclusion/Exclusion Criteria	
6. Data Sources & Methods of Data Collection	
7. Notes/Comments	

Survey Design

Another important piece of data collection may involve designing and administering a survey to capture information for the proposed project. Before embarking on survey development, it is helpful to outline what pieces of information it would be beneficial to capture and to assess the best ways of doing it.

Oftentimes, nuances in survey questions can result in eliciting very different responses. The survey questions need to be clear and easy to answer. It is important to keep surveys brief and in a format that will result in a high level of participation. It is also important to structure the questions in the optimal format for data analysis purposes and determine potential ways of analyzing the results ahead of time.

Helpful tools:

Questionnaire Design Tip Sheet

Selecting a Change Idea

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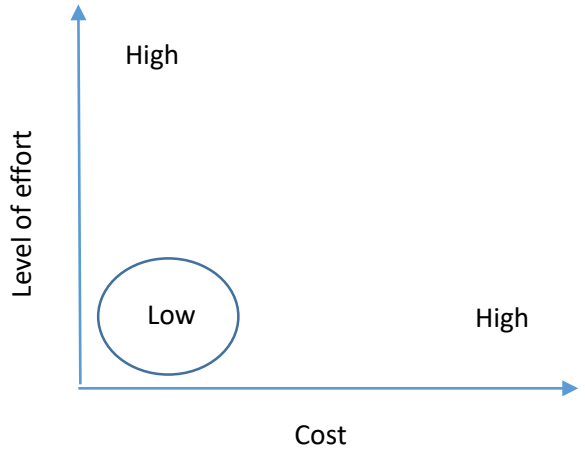
Once a list of change ideas has been generated in conjunction with the key driver diagram, it is time to select one to begin testing. It may be difficult to determine which idea to prioritize first. In those cases, it may be helpful to consider if there is an idea that stands out from all the others and assess if that selected idea has a high likelihood of resulting in an improvement.
The graph below can be used to help with the idea selection. Mapping out the level of effort and cost associated with each change idea can help identify any ideas that require a low level of effort and cost. It is recommended to start with those.



Helpful Tool: http://www.ihi.org/education/IHIOpenSchool/Courses/Documents/QI102_L4_APIChangeConcepts.pdf

Plan-Do-Study-Act Planning

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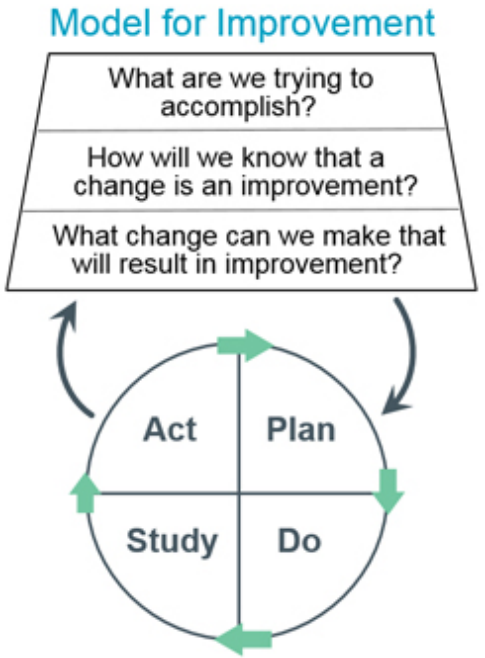
The process of testing can begin after the overall project goals have been defined and the data collection process has been laid out. Tests can be small to begin with to allow teams to go through the "bumpy" process before rolling them out on a larger scale. It is better to fail on a small test than on a process that happens across the organization.

Each test can be classified as a Plan-Do-Study-Act (PDSA) cycle. For those who are new to QI, it is advisable to use PDSA worksheets to track the cycles. This will help get into the rhythm of planning for tests of change and determining action steps for the next cycle. After enough experience, conducting PDSA cycles will become second nature.

What happens during each step?



Plan

- Briefly summarize what you plan to test. Determine who will be responsible for each piece and when the test will take place.

Do

- Conduct the test and document the results.

Study

- Compare your results to your baseline (if possible). Gather team members' input on how they thought the test went.

Act

- Decide what your team will do next. Pick one of the three A's: Adopt, Adapt, or Abandon. If you had success with this PDSA cycle, you may want consider adopting the change. If you believe the cycle needs further testing and/or refinement, you may decide to adapt it. If the test was unsuccessful and led to an undesired consequence, you may want to consider abandoning it.

Example of a small PDSA cycle:

1) The Cardiology team wants to improve the time it takes for their budgets to get approved. They test out a new team meeting structure that includes study team members and members from research finance. For their first PDSA cycle, they will see if having this meeting will reduce the number of questions that get asked over email during this step in the process.

See **example worksheet** on the next page to guide you through your next PDSA.

PDSA Example

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Team: HOPE Study Team	**Date of test:** 1/7/20
What is the overall project aim? To understand what participants are taking away from the HOPE trainings and how they are accomplishing their goals	
What is the objective of the test? To improve the survey response rate of a REDCap survey participants are sent via a postcard and QR code	

1) Plan

Briefly describe the test: Test out sending survey two weeks after vs two months after

How will you know that the change is an improvement?

Compare response rates between two groups.

What do you predict will happen?

Participants sent the survey two months after will respond better because they had more time to complete goal

2) Do

Test the changes. Did the cycle go as planned? ☐ Yes ☑ No

Record data and observations.

What did you observe that was not part of your plan?

Participants responded better two weeks after but left many questions related to their goal incomplete

3) Study

Did the results match your predictions? ☐ Yes ☑ No

What did you learn?

Better response rate isn't always better if the quality of the data is poor.

4) Act

Decide to Adapt, Adopt, or Abandon.

- ○ ***Adopt***: Implement change on a larger scale
- ◉ ***Adapt***: Improve the change and continue testing. Plan changes for next test.
- ○ ***Abandon***: Discard the change idea and try a different one.

Worksheet adapted from Christoff (2018)

PDSA Worksheet

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Team:	Date of test:
What is the overall project aim?	
What is the objective of the test?	

1) Plan

Briefly describe the test:

How will you know that the change is an improvement?

What do you predict will happen?

2) Do

Test the changes. Did the cycle go as planned? ☐ **Yes** ☑ **No**

Record data and observations.

What did you observe that was not part of your plan?

3) Study

Did the results match your predictions? ☐ **Yes** ☑ **No**

What did you learn?

4) Act

Decide to Adapt, Adopt, or Abandon.

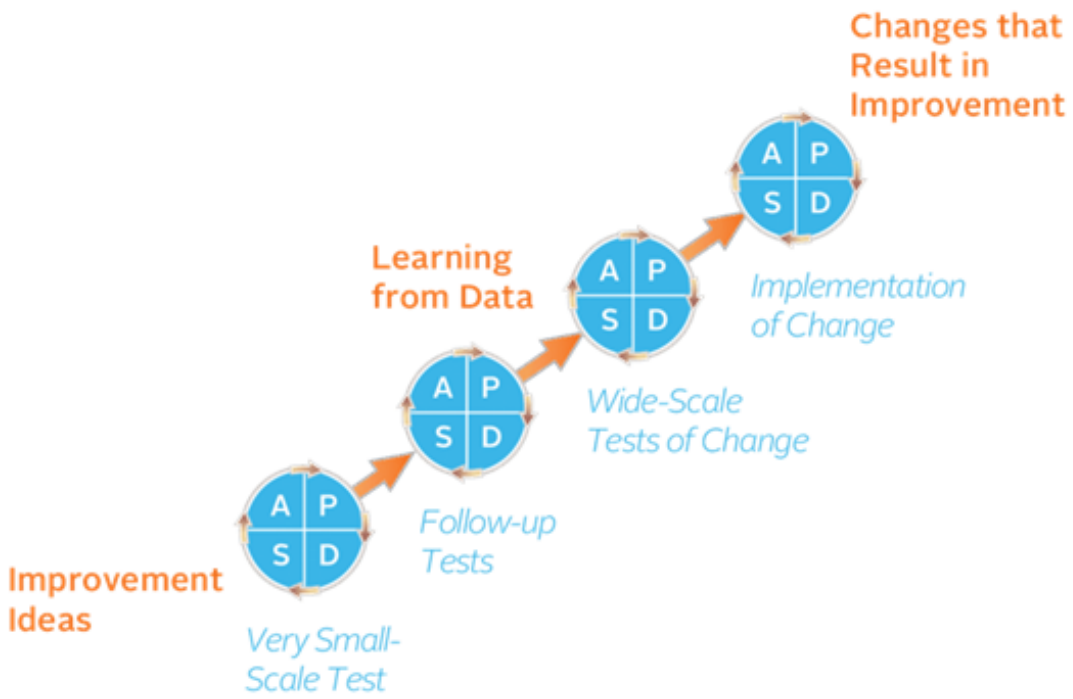
- ***Adopt***: Implement change on a larger scale
- ***Adapt***: Improve the change and continue testing. Plan changes for next test.
- ***Abandon***: Discard the change idea and try a different one.

Worksheet adapted from Christoff (2018)

Scaling Up

Once a selected change idea has been successfully tested out on a small scale, it may be time to scale up. Before doing so, it is important to recognize that the initial success is not a guarantee of future results. Therefore, it is recommended to incrementally increase tests to reduce the number of issues when scaling up.

If the proposed change is going to be uniformly adopted on a larger scale, it may be beneficial to consider involving administration or senior leadership to have the change formally adopted into policy. Moving towards formal implementation should be done only after the change idea has been successfully tested on a wider scale. An example of scaling is bringing your proposed change from one research department and testing it out in several additional departments.



Source: Quality Improvement Handbook A Guide for Enhancing the Performance of Health Care Systems

Monitoring Progress over Time

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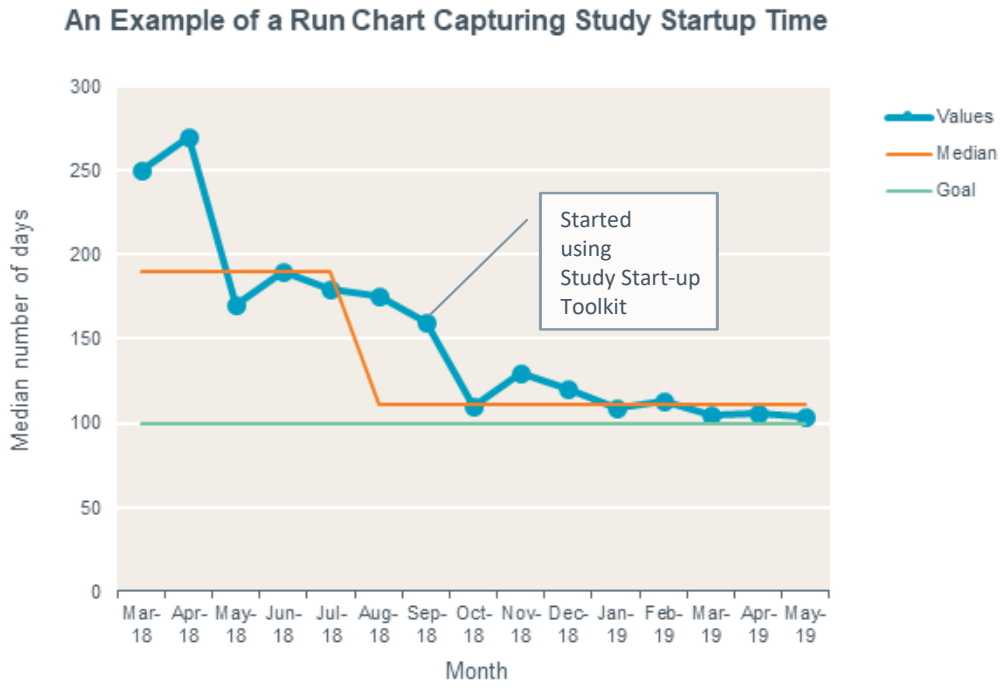
Once a change is implemented, it is critical to monitor its progress over time. Proactive monitoring will help track its effectiveness, increasing the team's accountability and ensure longer-lasting success. The best way to keep monitoring the change is to track it on a run chart. It is recommended to gather data and create run charts at regular intervals (e.g., weekly, bi-weekly, monthly, bi-monthly).

A run chart is a simple and effective tool for displaying progress made in a time sequence. Time is commonly plotted on the horizontal (x) axis and an identified measure of interest along the vertical (y) axis.

Using the median can help in the interpretations of shifts in a process over time.

Annotations ought to be used to help keep track of change ideas being tested.

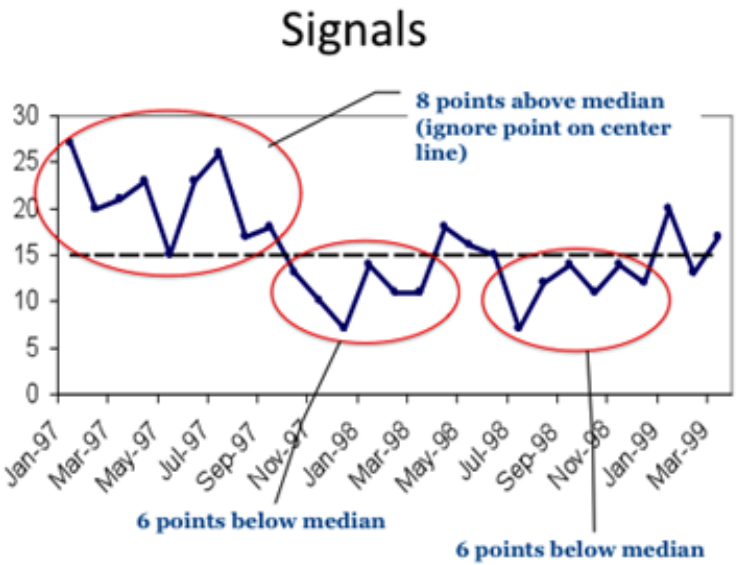


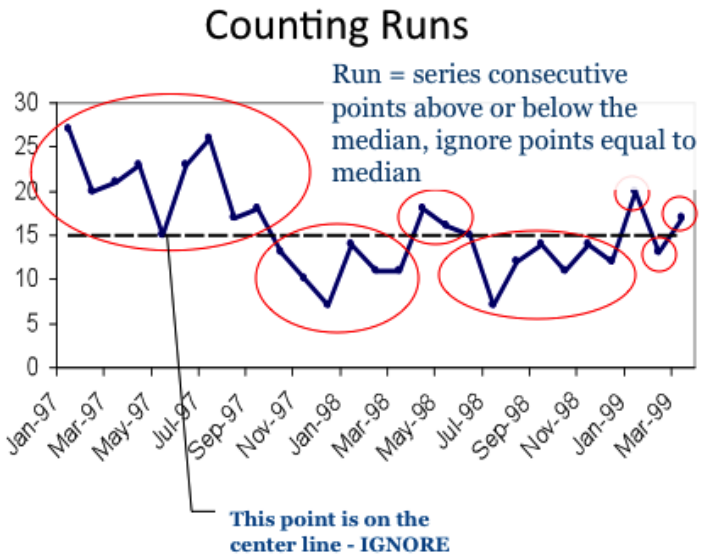
Run Chart Tools and Rules

There are different software programs (i.e. Minitab or QI Macros) which will help you with plotting your run chart, but the most basic option is to download an Excel Template provided by the Institute of Healthcare Improvement. On the second tab of that Excel document you will also see a list of run chart rules to help with the interpretation of the data.

The following all signal non-random variation in the process:

1) Shift = six or more consecutive data points either all above or all below the median
2) Trend = five or more consecutive data points in either ascending or descending order
3) Too few or too many runs
4) An astronomical point = a point that is clearly out of bounds. It is usually determined by a subject matter expert.

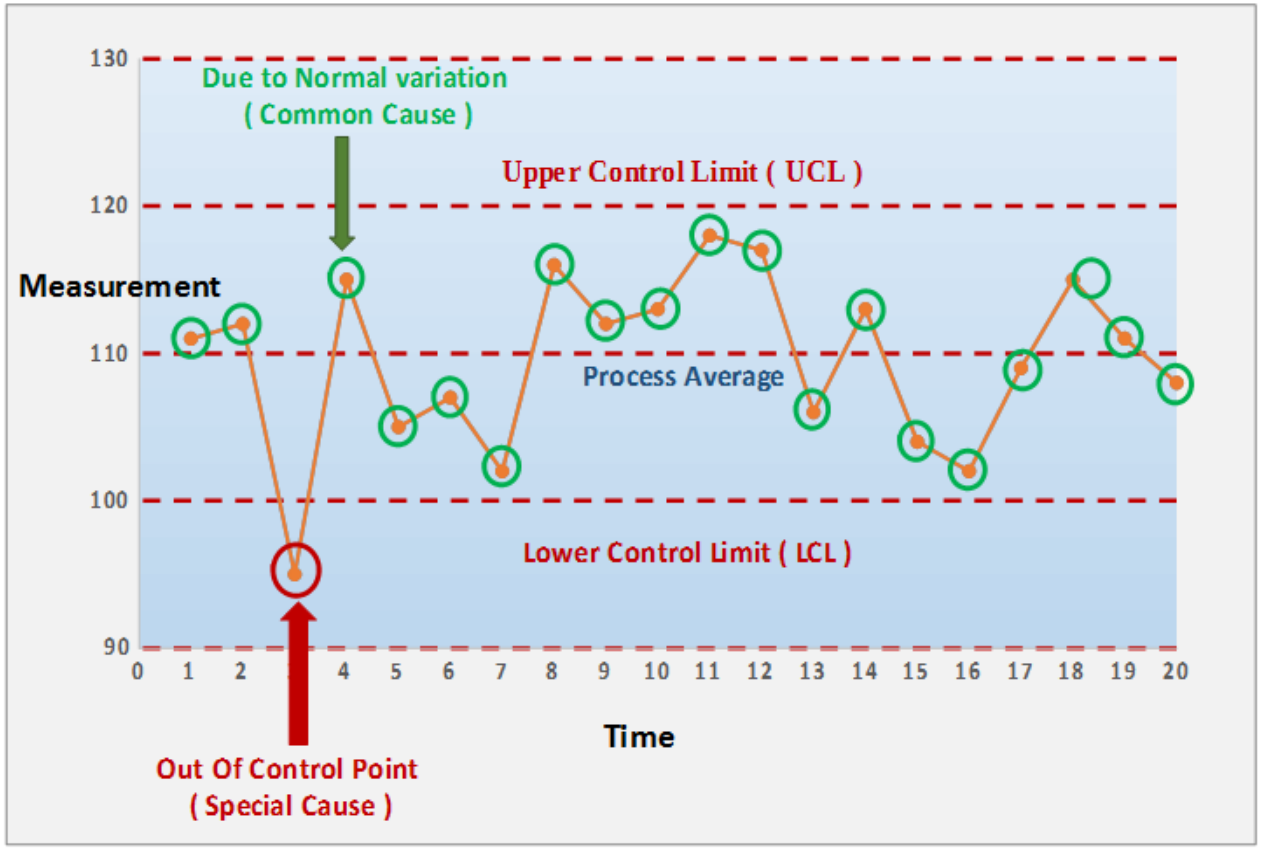




Source: Institute for Healthcare Improvement

Run Chart Interpretation

A normal process will have variation and several runs going above and below the median. If any of the rules or exceptions mentioned on the previous page take place, there is evidence of non-random variation. Such variation could signal a change in the process that may have been a direct result from something that was tested.
Monitoring the project's success on a run chart is an easy way to determine if the change idea being tested is resulting in an improvement.



Source: https://www.whatissixsigma.net/7-qc-tools/

Glossary

Cause-and-Effect Diagram:	A cause-and-effect diagram, also known as a fishbone diagram, displays the problem being addressed and all the underlying factors contributing to that problem. This graphical display can help organize brainstorms early on in a project.
Change Idea:	These are brainstormed strategies that need to be tested before being implemented. The change idea is expected to lead to an improvement, getting the team closer to achieving their project's overall aim.
Failure Modes and Effects Analysis (FMEA):	A FMEA is used to assess process failures and helps teams think through steps that could result in a failure. Prior to doing a FMEA, a team should make a process map. With a FMEA, each step is analyzed along with the consequences of each. The team also rates the likelihood of each process failure, the likelihood of detection and the severity if that failure were to happen.
Fishbone Diagram:	An alternative name for the cause-and-effect diagram. It displays the problem being addressed and all the underlying factors contributing to that problem.. This graphical display can help organize brainstorms early on in a project.
Gantt Chart:	A Gantt chart is a project management tool that displays project activities on the vertical (y) axis and the time frame for when each activity should be completed on the horizontal (x) axis. It is an alternative to a project timeline.
Key Driver Diagram:	A KDD is a diagram that displays the project's overall aim on the left and primary and secondary drivers on the right. Each driver is depicted in its own rectangle and arrows show the relationship between the drivers. Change ideas/change strategies related to the drivers will ultimately influence the project's overall aim. A KDD is often used as a roadmap for your overall project.
Plan-Do-Study-Act (PDSA) Cycle:	A PDSA cycle's four steps comprise what is essential for testing out a change idea: preparing to test the idea (plan), conducting the test (do), assessing the test's results (study), and determining what modifications, if any, need to be made to the test for future use (act). Depending on the test's results, the act step may involve adopting the change idea into practice as is, adapting and testing a variation of it, or abandoning it altogether. Therefore, it is recommended to start the cycles small and build up once there is more confidence in the change idea being tested
Process Map:	A process map is a visual depiction of the steps in a process. Arrows and additional symbols are often used to visualize the "flow" of the process. It is recommended to create a process map of the "current state" first and then map out their desired "future state." Mapping out the process of both current and future states can help identify redundant steps or inefficiencies in the process.

Glossary

Quality Improvement (QI):	QI is a systematic approach to improving processes and overall performance. There are several QI methodologies that share many of the same principles (e.g., Lean, Six Sigma, DMAIC and Model for Improvement). QI is frequently used to improve health care delivery, but it can also be adopted to improve processes in any field, including research.
Research Process Improvement (RPI):	RPI utilizes QI methodologies and tools to improve the performance of research studies.
Risk Profile Number (RPN):	A RPN is a number that is derived from multiplying the likelihood of a failure mode occuring (scale 1-10) x the likelihood that the failure is detected (scale 1- 10) x the severity of harm that would be caused by the failure (scale 1-10). The lowest number for a RPN is 1 and the highest is 1000. The higher the number, the higher the risk is if that step in the process fails. These numbers are used in a Failure Modes and Effects Analysis.
Run Chart:	A run chart is a basic line graph depicting a measure of interest over time with time usually being plotted on the horizontal (x) axis. This graph also shows the median. Basic statistical rules are used to interpret non-random variation in the process.
Specific, Measurable, Achievable, Relevant, and Time-bound (SMART) Objective:	SMART objectives refer to a set of robust objectives that are characterized by being specific, measurable, achievable, relevant, and time-bound. The objectives that are missing any of these five elements tend to be harder to achieve.

Further Reading

Tufts | CTSI Tufts Clinical and Translational Science Institute

7 Techniques for More Effective Brainstorming: https://www.wrike.com/blog/techniques-effective-brainstorming/

QI Essentials toolkit: http://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx

Run Chart Rules for Interpretation: http://www.qihub.scot.nhs.uk/media/529936/run%20chart%20rules.pdf

Stakeholder Analysis: https://www.pmi.org/learning/library/stakeholder-analysis-pivotal-practice-projects-8905

Implementation Strategies framework: https://implementationscience.biomedcentral.com/articles/10.1186/s13012-015-0209-1

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Institute for Healthcare Improvement. (2019). Run Chart Tool. Retrieved from http://www.ihi.org/resources/Pages/Tools/RunChart.aspx

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