

PHUSE CRO Summit: Improving the Attractiveness of a CRO Career

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ABSTRACT

The PhUSE CRO Summit was formed to identify the most critical issues facing CROs today and to determine how CROs can collaborate with PhUSE to address these issues. Leaders from top CROs gathered in focused discussion that included elements of Design Thinking and the Theory of Constraints Logical Thinking Processes to define the goals, objectives, and necessary conditions to solve our problem. Using these methodologies, the team decided on the goal of "improving the profile and attractiveness of a CRO career by fostering a positive culture that people want to join".

This poster will delineate the processes utilized by the group. We will describe the techniques used to choose our goal, our objectives, and the necessary conditions and obstacles to overcome for reaching our goal. The reader should come away with a clear understanding of our road map and project plan.

INTRODUCTION

The rapid pace of technological change presents a number of challenges, threats, and opportunities to the pharmaceutical industry. The pharmaceutical industry is now characterized by a dynamic landscape that continues to evolve with disruptive technologies, advanced methodologies and ever-increasing competition for talent both within and external to our industry. The PhUSE CRO Summit (PCS) was established in 2018 to determine the greatest challenges facing the CRO industry and how PhUSE can work with the CRO industry to overcome these challenges and take advantage of new opportunities.

The PSC held its kickoff meeting at the EU Connect Conference in Frankfurt in 2018. The summit brought together leaders of premier CROs that provide biopharmaceutical services. PhUSE invited leaders from the top CROs and providers supporting pharmaceutical companies with the aim of keeping the event controlled so that there is ample opportunity for networking and information sharing. In order to allow participants to speak as individuals, and to express views that may not be those of their organizations, and to encourage free discussion, the meeting was held under the Chatham House Rule. The Chatham House Rule is designed to facilitate open discussion of controversial topics by allowing participants to freely use the information from the meeting but forbidding participants from disclosing the source of the information.

Using the Chatham House Rule and Design Thinking methodology, the group came up with nine topics deemed central to the future of the pharmaceutical industry. From these nine topics the group derived a concise problem statement or goal to move forward with: "Improve the profile and attractiveness of a CRO career by fostering a positive culture that people want to join". This is the problem we chose to tackle at future summits and online collaboration.

PROBLEM SOLVING METHODS

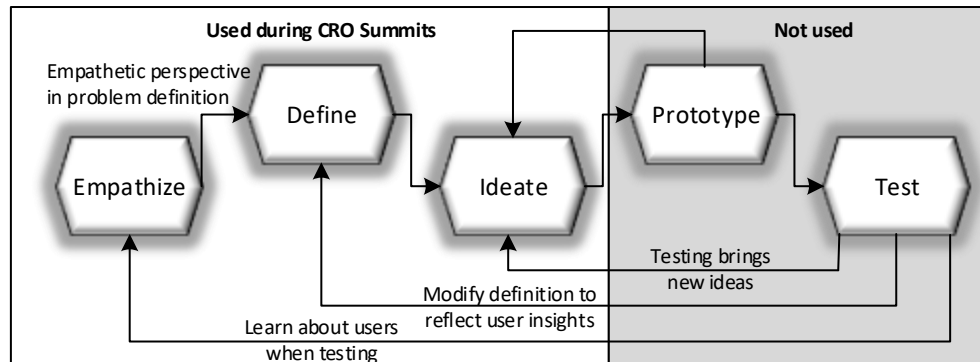
There are many methods used today for solving problems and lots of reasons for using one method or another. Perhaps you are trained in one more methods and you like to use them. Perhaps your employer or department head favors a particular method, so you comply. One cannot always take a one-size-fits-all approach to problem solving. Sometimes the best approach is to utilize a mix of methods that will suit your purpose. That is exactly what we have here in our poster showing our CRO Summit update. We took two very good problem-solving methodologies and applied the components that best served our purposes. This hybrid method may be quite useful going forward as we tackle more issues and opportunities facing our industry.

DESIGN THINKING

We wanted a way to facilitate out of the box thinking for our first PHUSE CRO Summit and decided on the Design Thinking Process. This was an excellent choice of methodology to use and it was masterfully applied by a couple of invited subject matter experts, and long-term PHUSE thought leaders, James McDermott and Ian Fleming. They facilitated an informative discussion followed by an excellent divergent-thinking exercise, using sticky notes, which ultimately resulted in the most important topics from our attendees' point of view. At that meeting in Frankfurt, the group was able to go through the first step in the process but did not have the time to craft a precise problem statement. We met a few months later in Baltimore and nailed down our problem statement which became the defined goal for which to lay out the roadmap. We weren't designing an app or software, so we didn't prototype or test

our solution. Instead we used the ideate stage to brainstorm some components of the Theory of Constraints Logical Thinking Processes (TOCTP) methodology integral to the roadmap leading to our goal.

Figure 1 – The Design Thinking Process



THE FIVE STAGES THAT MAKE UP THE DESIGN THINKING PROCESS

Empathize is the first step in the process and is typically handled through interviews with experts or users and should bring out the full context of the problem. As a group, our CRO Summit attendees were able to project how our resources feel about many aspects in a holistic look at the problem. By really listening to each other, we were able to identify many themes and topics where we might do better if we wanted to meet the needs of our resources across the industry. By taking an empathetic perspective we have defined the problem statement in a context suited to the right stakeholders.

Define is the step in the process where insights are garnered from the data. This is where we evaluated the “how might we” pain points discovered at our first meeting. During our second PCS in Baltimore, we looked at each grouping of these items and came together on a precise problem statement that represented our unmet needs. This became the goal of our analysis, “Improve the profile and attractiveness of a CRO career by fostering a positive culture that people want to join”.

Ideate is the part of the process where we brainstorm ways to address the problem. In order to stay focused during this brainstorming, we turned to the TOC TP methodology and broke down the goal into four parts:

1. Critical success factors leading to the goal.
2. Necessary conditions that must exist in order to accomplish each critical success factor.
3. Intermediate objectives that need to be met in order to create each necessary condition.
4. The constraints or obstacles standing in the way of each necessary condition that must be turned around thus defining our intermediate objectives.

Prototype was not done but is where representative forms of the solution are shared with the intended stakeholders in order to get their reaction and generate more ideas before moving into full development. This might be a nice place to integrate agile methods if the solution was a new software product.

Test follows, and was not done, but this is typically where stakeholders are presented with a prototype or actual solution to see how the problem is solved and if there are remaining or new pain points. Testing might send feedback all the way to the beginning where the process will begin again until the solution solves the right problems or brings relief to frustrations with the current solution or prototype.

THEORY OF CONSTRAINTS LOGICAL THINKING PROCESSES

The Theory of Constraints Logical Thinking Processes were developed and refined in the early 1990s by Dr. Eliyahu M. Goldratt, author of the bestselling business novel “The Goal”. The Theory of Constraints was basically developed to maximize overall throughput in manufacturing processes but the TOCTP may be applied universally. You can think of the TOCTP as a method for putting some structure to simple common sense. Dr. Goldratt said, “An expert is not someone who gives you the answer, it is someone who asks you the right question.” The TOCTP is a natural extension anywhere in the Design Thinking process for those experts who know how to empathize and define problems from the context of the stakeholders. When followed through to the end, the artifacts of the TOCTP give the overall vision with the goal tree and an overall road map to success that not only tells what needs to be done but also states why as can be found in the Intermediate Objectives Map (IO). People are much more likely to complete an action correctly if they know why the action needs to be taken. The IO map is also known as the Prerequisite Tree by TOC purists, but it is so much easier to refer to it as the IO map as it rolls off the tongue so much easier.

There are many logical trees associated with the TOCTP and at the root of each, pun intended, is the concept of “sufficient cause” and “effect-cause-effect” logic. Within the trees, shapes have an “and” relationship when the arrow lines are circled. An “or” relationship is designated by not circling the arrow lines. For example, in Figure 2 below, Goal01 is the result *because* of CSF01 and CSF02 and so forth. You can see how all the arrows are circled going into the shape for Goal01. Logically, there may be many causes or reasons for a result like this. One could potentially add dozens of shapes, but as a rule, only add shapes that capture the biggest causes, until you have described fully the cause and effect logic within reason. There is no need to go into minutia because that level simply doesn’t add value to the analysis.

One of the nice things about the TOCTP is that you only use the trees when necessary. Basically, you just need to describe; “what to change?”, “to what to change?” and “how to cause the change?” as efficiently as possible. In this endeavor we only needed to use the Goal Tree, a few IO Maps and a list of obstacles under each necessary condition. Examples can be seen in the figures below.

Figure 2 – The TOCTP Goal Tree

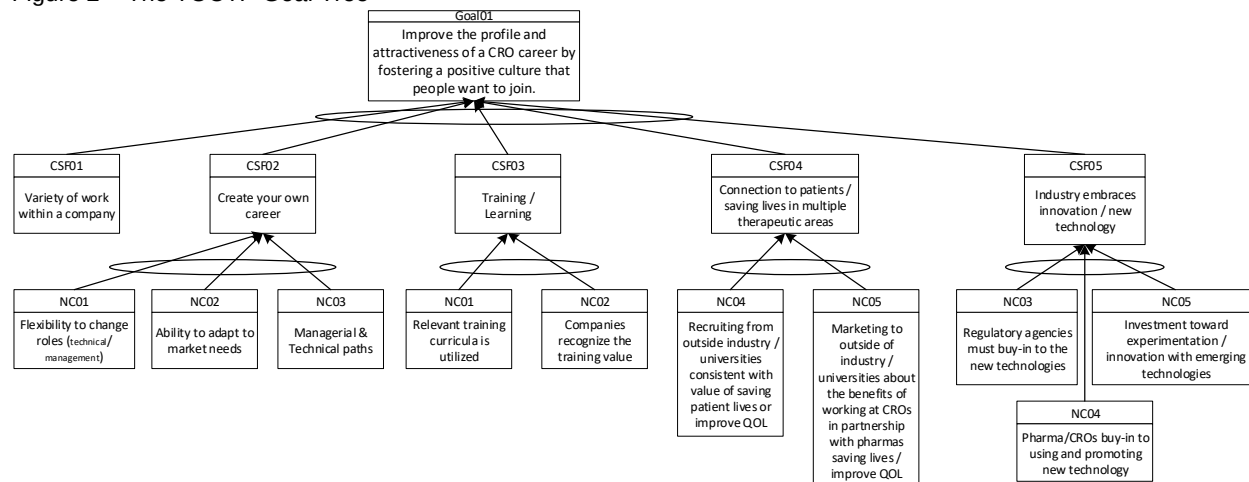
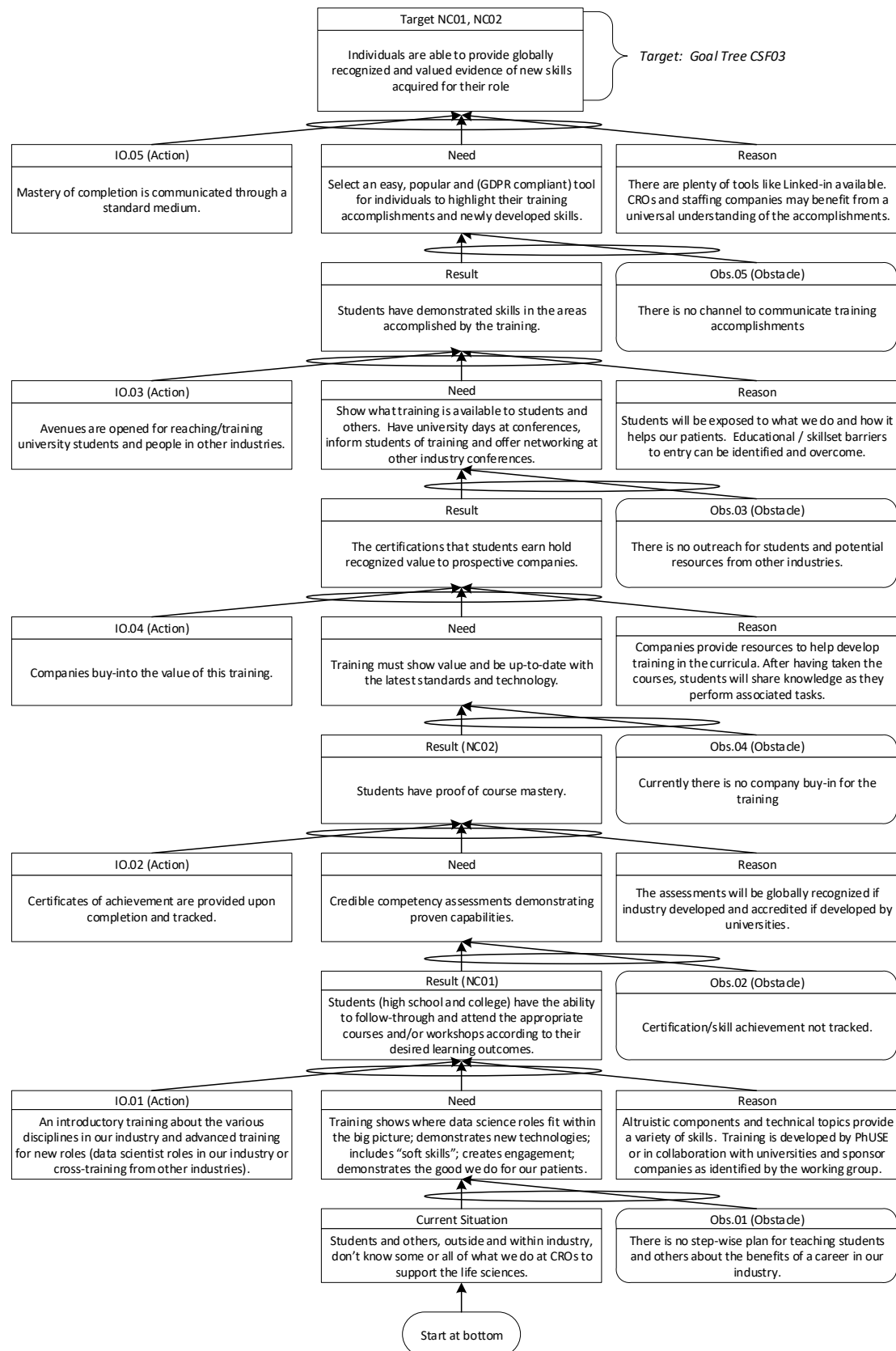


Figure 3. Obstacles List

The sequence to complete objectives is top down. Numbers are just identifiers.

Obstacle	Intermediate Objective	Necessary Condition
01. There is no set curricula for industry	01. An introductory training about the various disciplines in our industry and advanced training for new roles (data scientist roles in our industry or cross-training from other industries).	NC01. Role based training curricula is utilized
02. Certification/skill achievement not tracked	02. Certificates of achievement are provided upon completion and tracked	NC02. Companies recognize the training value
04. There is no company buy-in for training	04. Companies buy into the value of this training	NC02. Companies recognize the training value
03. There is no outreach to universities	03. Avenues are opened for reaching/training university students and people in other industries	NC01. Role based training curricula is utilized
05. There is no channel to communicate training accomplishments	05. Mastery of completion is communicated through a standard medium	NC02. Companies recognize the training value

Figure 4. Intermediate Objectives (IO) Map



GOAL01

We used the “goal tree” displayed in Figure 2 to organize and present our results. Using the methods described above, we defined five critical success factors (CSFs) for reaching our goal. These are shown in Figure 1. and are labeled CSF01 - CSF05. The five CSFs we identified were:

- Variety of work
- Create your own career
- Training and learning
- Connection to patients/saving lives through product development
- The industry embraces innovation and new technology

Next we identified the necessary conditions (NCs) required to meet each CSF. To illustrate how to use our goal tree, our discussion will use CSF05 (the industry embraces innovation and new technology) as an example. There were many assumptions that we documented on the poster for each CSF. We placed cryptic text on our working Goal tree as we met to discuss the necessary conditions and how they lead to the critical success factors. It is always a good idea to bring the assumptions out into the open when developing cause and effect logic.

CSF05

We derived three necessary conditions (labeled NC03, NC04, and NC05). As you can see in Figure 2, the arrows are circled. Therefore, an “and” relationship exists for all three of the following necessary conditions to exist for the critical success factor, CSF05, to exist.

- Regulatory authorities must buy in to the new technologies
- Pharma/CRO must also buy in to using and promoting new technologies
- Pharma/CRO must invest in experimentation/innovation with new technologies

You can read the logic from top down in this map and would say that Goal01 is met because all five critical success factors, CSF01-CSF05, are in place. Critical success factor CSF05 exists because NC03, NC04 and NC05 are in place.

OBSTACLES

Figure 3 shows the list of obstacles that needed to be overcome in order to create the necessary conditions that roll up to critical success factor CSF03 (relevant and recognized training existing for industry). We talked about each necessary condition with empathy and tried to understand how they fit with our stakeholders. Then we teased out the potential obstacles that stood in the way. We settled on the important obstacles and listed them out. Then we turned each obstacle 180 degrees to create an objective. The key to this step was to understand what was in the way and then simply, as a matter of fact, state the opposite (giving the objective) as if it were already done. The resulting list of objectives were then ordered logically by precedence. That is, the objectives that had to be in place first came before the other ones would begin. This list was then the basis of the IO map in Figure 4.

INTERMEDIATE OBJECTIVES

The way to read an IO map is to start from the bottom of the map and work your way up. At the bottom, you can see the current situation and right next to it is the obstacle. We looked at the situation and the obstacle and determined the need. We went upwards in the logic starting at the bottom. We identified the need and then turned around to test our logic. That is, we stated there is a need for training showing what we do in industry because currently students and others outside our industry don't know what we do and there is no stepwise plan for teaching them. We made sure that logic was correct and then we settled upon the appropriate action to take which would then give us the result we were looking for, that is, giving the opportunity for students to have training available. We provide the reason behind performing the action, in this case it provides a variety of skills, pulls on the heartstrings with an altruistic component and is developed in collaboration with PHUSE colleagues and universities. At that point we reached a result which then became the current situation in the roadmap. Then the process started again with the next obstacle, need, action, reason and result. We continued until we reached the very last result and that was the necessary condition feeding into the critical success factor. This process was repeated for all of the rest of the necessary conditions leading to the other CSFs. CSF01 was outside the scope of PHUSE so the assumption was that individual companies would reach that CSF in order to reach their goal.

CONCLUSION

This project is still in progress, as the group is working to complete the goal tree displayed above. Our goal is to complete the tree and present the finished product to the PHUSE Steering Committee so that the items we identified may be incorporated into the PHUSE Working Groups and completed to meet our necessary conditions. We will have this paper and the associated poster available and are willing to create a white paper if necessary. This may not be necessary because we feel that we have the information necessary in the paper and the poster.

By the using mixed methodologies we were able to define the most pressing issues facing CROs today. We were also able to find opportunities that will benefit our industry in the future. We've defined how to capitalize on these opportunities through our roadmap and how we turned around the obstacles and created intermediate objectives to breakthrough any of the constraints standing in our way forward. The IO map is very useful because it is basically a work breakdown structure that can be shared with a project manager. It not only states what to do, but also states why, and that gives a good chance of getting the tasks and actions done right the first time.

We met at the CRO Summits and then met as a group monthly to create the roadmap of actions and the reasons behind the actions in a very short time. Because most of our roadmap is visual it is easy to communicate with others in a way that is simple to understand. Upon completion, the goal tree and logic trees beneath it provide the complete picture and can be used directly as a project plan. At the very least, it is useful cut-paste input to any project plan template. By merging these methods to fit our circumstances, we have developed the roadmap to address our goal: "Improve the profile and attractiveness of a CRO career by fostering a positive culture that people want to join."

ACKNOWLEDGMENTS

We'd like to thank the attendees of our CRO Summit meetings for their hard work and continued dedication during our monthly meetings as we collaborated to create the roadmap to our shared goal.

RECOMMENDED READING

The Goal, The North River Press Publishing Corporation, P.O. Box 567, Great Barrington, MA 01230.

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