System dynamics applied to oversight of ongoing project: a case of Clinical Trials Programming

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ABSTRACT

It has been proven that System dynamics models accelerate the efficiency of project management. The examples of project managements applied System dynamics in business planning and developments or manufacturing settings have been seen many before, but the examples of oversight of a ongoing project have not. This paper applied System dynamics to ongoing Clinical Trials Programming. Clinical Trials Programming is a part of processes of a new drug development. Because the outputs from the process are required high quality, the model has specific processes like double programming and ongoing quality check. And this ongoing quality check process brings reworks. The reworks have been thought problem from the perspective of project management. But a key factor which occurs the reworks in the process has not indentified with any evidences. Then the objectives of this research are to identify the key factor which occurs problems in the process using the model and to confirm that System dynamics contribute to oversight of the ongoing project. Through the discussion of this research, it was identified that the rework rate in the late stage of the process is the key factor and confirmed the contribution of System dynamics to oversight of the ongoing project.

Keywords: Project management, Rework, Oversight, Clinical Trial Programming, Double programming, Ongoing project. Key factor

INTRODUCTION

System dynamics models have proven their values in contributing to not only simple but also complex development projects. Especially, the examples of project managements applied System dynamics in business planning and developments or manufacturing settings have been seen many before. But the researches focused on the way of oversight of ongoing project with System dynamics have rarely seen. And, as the example application in this paper, System Dynamics was applied to project management of Clinical Trials Programming. Clinical Trials Programming is to generate statistical programming codes and the tables and figures using statistical analysis software and clinical trials data. It is a part of the activities in order to get approval for new drug through submission to the each country authority like FDA in US. The outputs from the program codes are reviewed and compared with correspondent outputs due to the demands of high quality. As a result of this ongoing QC process, some reworks are occurred. Those reworks on ongoing project will make troubles in the schedule, cost and manpower. The reworks have been thought problem from the perspective of project management. But the key factor which occurs the reworks in the Clinical Programming process has not indentified with any evidences. Then, the objectives of this research are to identify the key factor which occurs the reworks in the project using the System dynamics model and to confirm that System dynamics model contribute to oversight of the ongoing project from the perspective of project management.

In the next section, literature review is executed. It would be related to applying System dynamics to project management. And the section 2 shows how to designing the System dynamics model for the Clinical Trials Programming. Basically, it is based on the first rework cycle model (Cooper 1980, 1993) and additionally modified to have the flow of double programming and ongoing quality review process. In Section 3, the simulations are executed. The method of the simulation is sensitivity analysis. And after that, an example of oversight of the ongoing project is discussed with the analysis of the simulation results in Section 4. And at last, the summary of this research and further research will be mentioned.

2 LITERATUE REVIEW

The relationship between project management and System dynamics has been more than 20 years. System dynamics models have proven their values in contributing to not only simple but also complex development projects. And there are researches which discussed System Dynamics in the area of project management. A paper said that one of the most successful areas for the application of System Dynamics has been project management. this paper measured both in terms of academic research and real-world applications. (Lyneis JM et al., 2007). Another paper showed that System dynamics models facilitate the strategic management of projects, including planning the project, determining measurement and reward system, evaluating risks and learning from past projects with a case study of the Peace Shield Air Defense System (Lyneis JM et al., 2001). And there is a research paper with examples from a model of the commercial jet aircraft industry which concluded that the use of System Dynamics models for forecasting allows managers to 1) get an early warning of industry structural changes, 2) identify key sensitivities and scenarios and 3) determine appropriate buffers and contingencies for forecast inaccuracies (Lyneis JM, 2000). As seen above, the value in contributing to significantly improved project performance when System Dynamics is applied to project management has already proven. And those researches mainly illustrated about the proof of efficiency when System Dynamics is applied to project management. But we have rarely seen the example of oversight of ongoing project from the perspective of project management with System Dynamics. So, this paper shows an example of using System Dynamics applying to oversight of ongoing project in a case of the Clinical Trials Programming.

3 DESIGNING SYSTEM DYNAMICS MODEL FOR ONGOING CLINICAL TRIALS PROGRAMMING

3.1 Outline of the Clinical Trials Programming

The work flow of Clinical Trials Programming is shown as Figure 1.

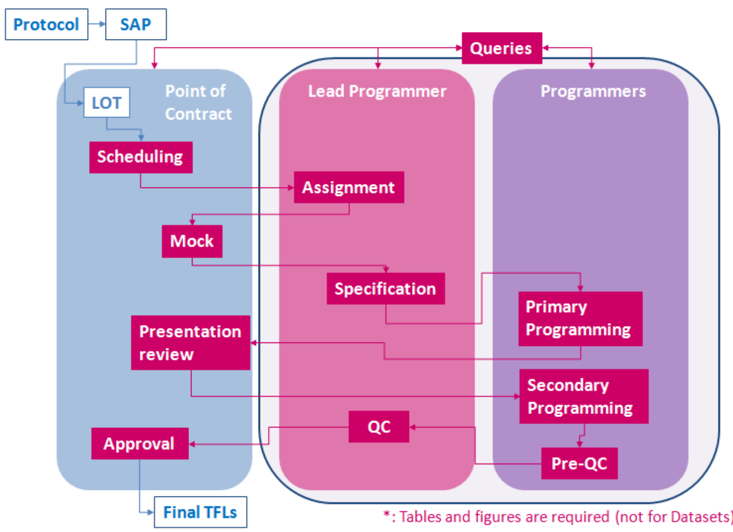


Figure 1. Clinical Programming Work Flow

Clinical Trials Programming will be done by flowing the Clinical Trials Protocol and the Statistical Analysis Plan (SAP). The person who is Point of Contract (POC) role generate a List of Tables (LOT) depends on the Protocol and SAP. And after the timeline for the Clinical Trials Programming depends on the LOT is defined, A lead programmer and the other programmers are assigned. Mock tables which are the draft presentations of the tables & listings are generated before creating the program codes. And the specification of programming for the analysis are also. Then, primary programmer will generate program codes following the SAP, LOT, Mock and Programming Specifications using a statistical analysis software SAS. When a set of tables & listings are generated, POC will review the presentations in order to keep consistency between the plans, which are described in the Mock and Programming specifications, and outputs from the program codes. After confirming the presentation by POC, secondary programmer will generate program codes for quality control (QC). The QCs are done by programmers first. And lead programmer and POC approve the tables & listings finally. Those outputs are called final Tables, Figures and Listings (Final TFLs).

3.2 Designing SD model of Clinical Trials Programming

This section describes the System Dynamics model of Clinical Trials Programming. First of all, the System Dynamics model of Clinical Trials Programming is based on the first rework cycle model shown conceptually in Figure 2 (Cooper 1980, 1993). The rework cycle's recursive nature in which rework generates more rework that generate more rework, etc., creates problematic behaviors that often stretch out over most of project's duration and are the source of many project management challenges (Lyneis JM et al., 2007).

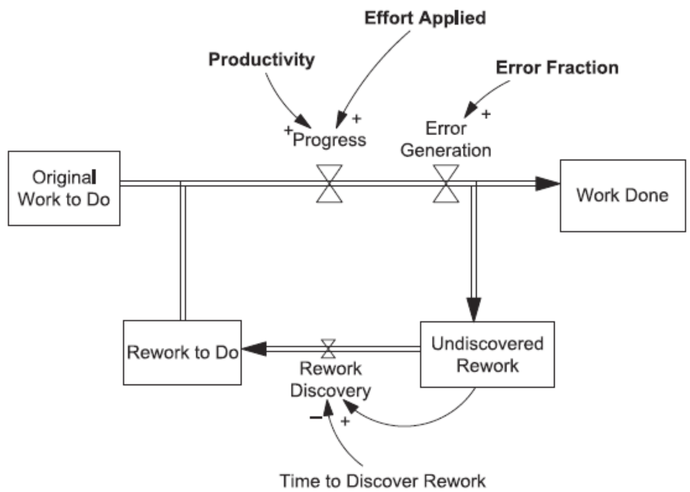


Figure 2. The first rework cycle (adopted from Cooper, 1993)

The System Dynamics model of Clinical Trials Programming in Figure 3. is the basically the same as the first rework cycle model in Figure 2. At the start of the project, all work resides in the stock "Table ready for programming". Progress is made by applying effort. A fraction of the work being done at any points in time contains errors. Work done correctly enters the "Tables Really Done" stock and never needs rework unless later changes render that work obsolete. However, work containing errors enter the "Re-work (Primary Programming)" stock. Errors are not immediately recognized, but are detected as a result of doing downstream work or checking. This downstream work or checking will occur hours or days after the rework was created. Once discovered, the backlog of reworks demands the application of additional effort. Reworking an item can generate or reveal more rework that must be done. Therefore, some reworked items flows through the rework cycle one or more subsequent times.

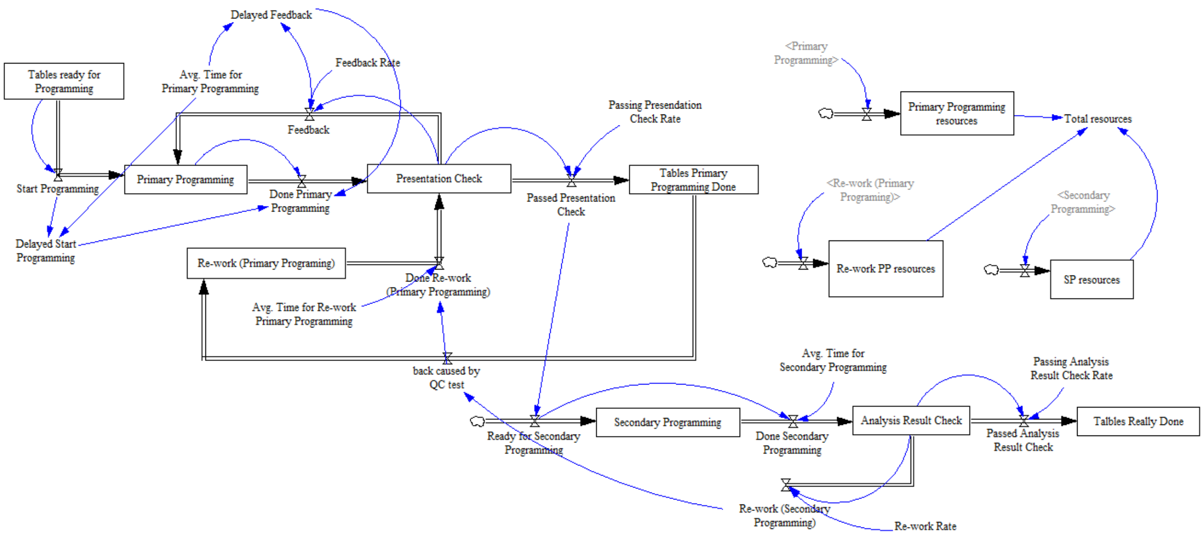


Figure 3. System Dynamics model of Clinical Trials Programming

As just described above, the rework cycle concept in Clinical Trials Programming is the same as Cooper's the first rework cycle model. But the feature of the System Dynamics model of Clinical Trials Programming is that it has double programming process and two part of ongoing quality check processes in the model. In order to fulfill the demands of quality against the results which are tables and figures from the generated program codes, the model includes the specific flow of double programming. And also, the model included two part of ongoing quality check processes. Those quality check processes are "Presentation Check" and "Analysis Result Check" stocks. And those ongoing quality check processes bring some reworks of programming as previously described.

3.3 Main parameter setting

This section describes the System Dynamics model of Clinical Trials Programming. First of all, The main parameters setting as a default for the System Dynamics model of Clinical Trial Programming is shown in Table 1.

Table 1. Default setting of the parameters

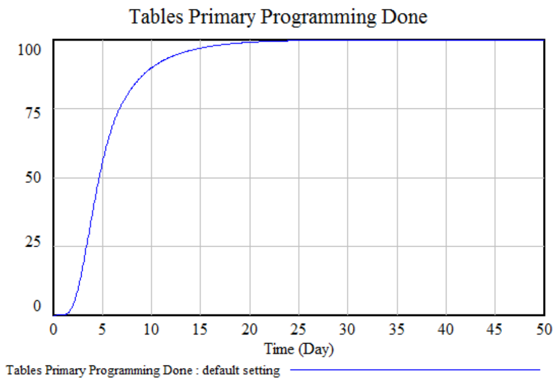
Variables	Type	Value/equaion	Descriotion
Tables ready for Programming	Stock	100	Table numbers which is needed to generate
Delayed Start Programming	Rate	DELAY N(Start Programming,"Avg. Time for Primary Programming", 0 , 5)	
Feedback Rate	Auxiliary	0.2	
Delayed Feedback	Rate	DELAY N(Feedback, "Avg. Time for Primary Programming" , 0 , 5)	
Done Secondary Programming	Rate	DELAY N(Ready for Secondary Programming, "Avg. Time for Secondary Programming" , 0 , 5)	
Re-work Rate	Auxiliary	0.2	

File name of model with Vensim: Rework03B3-re03-BCN03.mdl

In this research, The total number of tables and listings are set 100. And other stock like "Primary Programming" is set initial value 0 (zero) because no talbe and listings are generated at the begging of this flow.

3.4 Basic simulation results

The basic simulation results using the setting of the default parameters of the System Dynamics model of Clinical Trials Programming in section 3.3 is shown in Figure 4. Those are the basic results in this research.



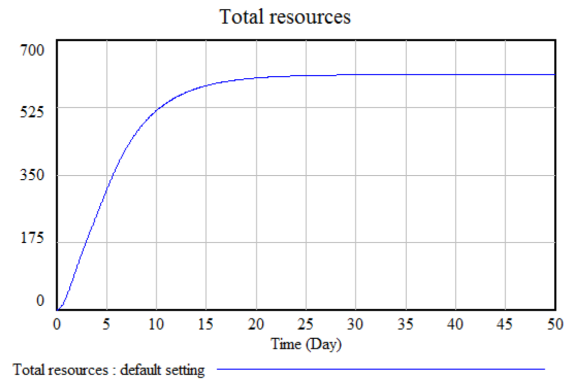


Figure 4. Simulation results using default parameter setting

In this case, the stock of "Table Really Done" started from 0 (zero) and ended 100 in the model. This shows the number of tables and figures which are generated though this process. And the "Total resources" value ended around 610 hours. Actually, the real-world project of Clinical Trials Programming, about 100 tables are generated by 3.5 programmers within 3 months from when the mock and programming specification of the tables and listings are provided. The 610 hours are almost equal to 175 hours in a month versus 3.5 programmers. Then this System Dynamics model and the default parameter seems to be consistent with the real-world activities of Clinical Trials Programming.

4 EXAMPLE APPLICATION

In this Section, some scenarios of the best way of using System Dynamics applied to oversight of ongoing project management with a case of the Clinical Trials Programming through identifying the measurement to evaluate risks over the project to improve the project performance is discussed.

4.1 Purpose of the simulations

The purpose of the simulations will be to find the factors which affect the performance of project management strongly using the System Dynamics model of Clinical Trials Programming with sensitivity analysis.

4.2 Important features of the Clinical Trials programming model

As described in the previous sections, there are two important features in the Clinical Trial Programming process. In this section will explain that in detail a little bit.

① Double Programming process: in order to fulfill the demands of quality against the results which are tables and figures from the generated program codes, the model included the specific flow of double programming. The double programming will be done by two or more programmers. The primary programmer(s) will make the official outputs which are reviewed by POC and confirmed not only the values of analysis results but also the presentations of tables and listings. And the other programmer(s) will make the outputs for checking the results as secondary programmer(s). Then the results from primary programmer(s) and secondary programmer(s) will be check the consistency between them to keep the quality of analysis results using the same programming specification.

② Ongoing QC check process: the model included ongoing quality check processes which are "Presentation Check" and "Analysis Result Check" stocks. This ongoing quality check process brings some reworks of programming as previously described in the part of the first rework cycle model.

Those two important features will affect the quality, cost and schedule each other in the project. But the strength of impact which is affected by the two features does not understand easily due to the rework cycle's recursive nature. So, next section will discuss which factor will affect the impact stronger than others using the System Dynamics model of the Clinical Trials Programming.

4.3 Parameter setting in the simulations

The default setting of the parameters in the System Dynamics model of Clinical Trial Programming is the same as shown in Table 1 of section 3.3. But some changes in the parameters which are related to rework rates will be added depends on the interest of this research. The modified setting describes in the section 4.5.

4.4 Methodology of finding the factors which affect the performance of project

Simulations with sensitivity analysis will be done in this research. The following simulations will be executed by using the System Dynamics model of Clinical Trials Programming with the default setting basically, but some changes are found in the parameters which are related to rework rates after the two checking points "Presentation Check " and "Analysis Result Check ". Because those two processes will occur the rework activities and affect the cost, quality and schedule in this Clinical Trials Programming project. Such a kind of analysis which is changing the parameters to find key factor which affects the results strongly in the same model is called sensitivity analysis.

4.5 Simulations

The purpose of simulations is to find key factor which affect the cost, quality and schedule strongly in Clinical Trials Programming using the System Dynamics model. As described above, one of the feature of this model is ongoing QC check process which brings some reworks of programming. So, this research focus on the two variables, "Feedback Rate" and "Re-work Rate", those variable are exist after the two checking points "Presentation Check" and "Analysis Result Check".

Table 2. Setting of sensitivity analyses

Simulation No.	Variables name	Variable Type	Model value	Range	Equation
1	Feedback Rate	Auxiliary	0.2	0-0.5	=RANDOM_UNIFORM(0.0.5)
2	Re-work Rate	Auxiliary	0.2	0-0.5	=RANDOM_UNIFORM(0.0.5)

Simulation 1: check the strength of impact which affects the project performance of the variable of "Feedback Rate" which is exist after "Presentation Check" stock in the model.

In the simulation 1, one parameter, "Feedback Rate", which exists after "Presentation Check" is one of the features of this model and this research focus on will be given some changes to see the impact to the values of "Tables Really Done" stock and "Total resources" variables. Because those two values show the performance of this project.

The settings of the sensitivity analysis in Simulation 1 are described in Table 2 as Simulation No.=1.

The simulation results using the setting above are shown in Figure 5.

S1-A: Tables Really Done   S1-B: Total resources

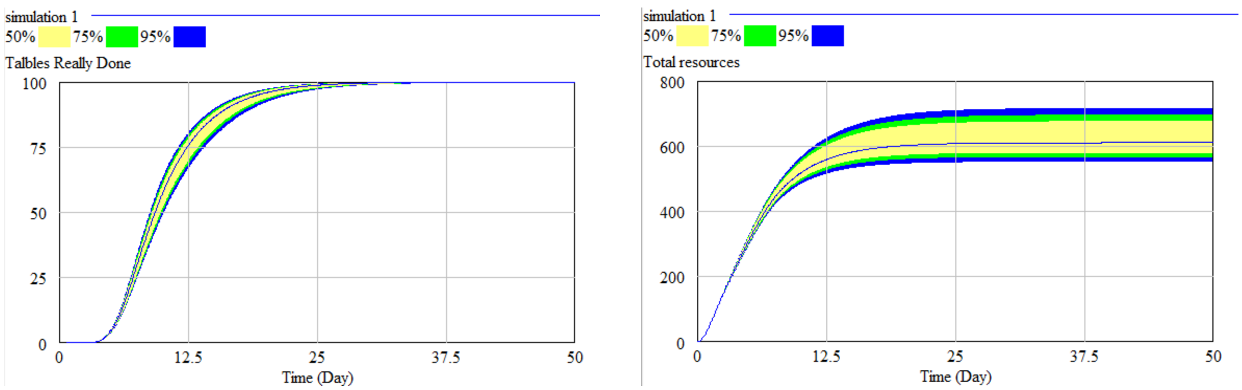


Figure 5. Result of Simulation 1

From the results of simulation 1, the progress of this project is shown as number of tables in the variable "Tables Really done". And the total manpower is shown in "Total resources" variable. The x-axis of both figures shows Time(Day) from 0 to 50. The y-axis of the figure of "Tables Really Done" shows the number of tables and "Total resources" shows the cumulative number of manpower(hours). The lines in the figures show the range of results which come from sensitivity analysis using Monte carlo simulation. The number of simulation is 200 times.

The range of y-axis in the figure of "Tables Really done" is about 70 to 80 at 12.5 days of the x-axis. And the range of y-axis in the figure of "Total resources" is about 550 to 700 hours at 25 days of the x-axis. Those range covers 95% of the results which are produced by the Monte carlo simulation using the System Dynamics model of Clinical Trials Programming.

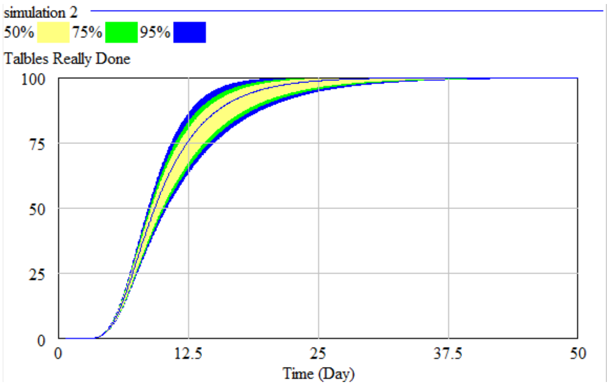
Simulation 2: check the strength of impact which affects the project performance of the variable of "Re-work Rate" which is exist after "Analysis Result Check" stock in the model.

In the simulation 2, one parameter, "Re-work Rate", which exists after "Analysis Result Check" is one of the features of this model and this research focus on will be given some changes to see the impact to the values of "Tables Really Done" stock and "Total resources" variables as it is seen in the simulation 1.

The settings of the sensitivity analysis in Simulation 2 are described in Table 2 as Simulation No.=2.

The simulation results using the setting above are in Figure 6.

S2-A: Tables Really Done



S2-B: Total resources

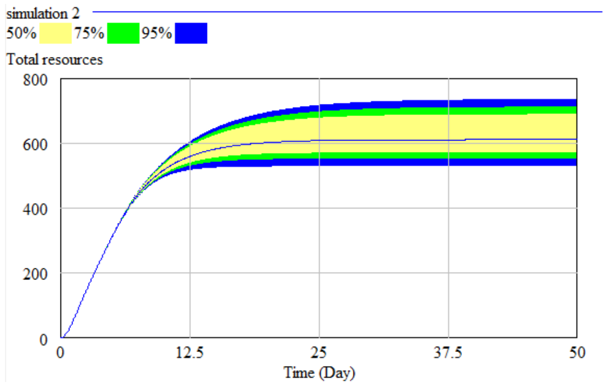


Figure 6. Results of Simulation 2

From the results of simulation 2, the progress of this project are also shown. The simulation method is the same as simulation 1. The number of simulation is 200 times.

The range of y-axis in the figure of "Tables Really done" is about 62.5 to 87.5 at 12.5 days of the x-axis. And the range of y-axis in the figure of "Total resources" is about 500 to 750 hours at 25 days of the x-axis. Those range also covers 95% of the results which are also produced by the Monte carlo simulation.

4.6 Simulation results summary

Two simulations are executed above. The summary listing is shown as Table 3. Big differences are seen in the range column of the results.

The settings of parameters in the model except the variables "Table Really done" and "Total resources" are all the same as default setting in section 3.

Table 3. Summary of simulation results

Variable	Simulation No.	x-axis value (time(day))	y- axis (tables)			
			Lower value*	Upper Value*	Range	Unit
Tables Really done	1	12.5	70.0	80.0	10.0	Tables
	2	12.5	62.5	87.5	25.0	
Total resources	1	25.0	550.0	700.0	150.0	Hours
	2	25.0	500.0	750.0	250.0	

*: covers 95% of simulation results

In the summary table, the values of x-axis are also used the same points when the performance (values of y-axis) is compared between those two results. In this case, the big differences of the range in the column of y-axis are seen in the summary results. That is the range of simulation 1 in the row "Tables Really done" is 10 tables and simulation 2 is 25 tables. And the range of simulation 1 of "Total resources" variable is 150 hours and simulation 2 is 250 hours. The reasons why the differences have occurred are discussed in the next section.

5 Discussion

In the previous section, the big differences are seen in the summary results. The ranges of simulation 2 are larger than simulation 1 in the both two variables, "Tables Really done" and "Total resources". In this section, the interpretation of the simulation results and explanation of impact of the two factors which are "Feedback Rate" and "Re-work Rate" to the projects are discussed.

To explain those, some explanations of the actual activities of this project regarding "Tables Really done" variable will be needed. Once the project are started, the programmers should have generated around 70 to 80 tables by the time of 12.5 days after starting the project in the case of simulation 1 and also around 62.5 to 87.5 tables should have generated in the case of simulation 2. Otherwise, the project dose not going well. And as well as regarding "Total resources" variable, the cumulative total resource will be around 550 to 700 hours in case of simulation 1 and 500 to 750 hours in simulation 2. The important thing is the range of simulation 2 is wider than simulation 1.

As a perspective of project management, it is easy to manage when the variance of the each task is small. This mean the smaller ranges like the results of simulation 1 will be preferred by project manager rather than the simulation 2. And as a perspective of sensitivity analysis, comparing with simulation 1, simulation 2 which was set "Re-work Rate" variable as the parameter is more sensitive to reduce the project performance.

So, from those results of simulations, the "Re-work Rate" variable has stronger impact than "Feedback Rate" variable. The "Re-work" variable is located just after "Analysis Result Check" variable in the late stage of this programming process. On the other hand, the "Feedback Rate" variable is located just after "Presentation Check" variable in the early stage of this process. This mean that the rework rate in the late stage of this project which "Re-work Rate" is located has larger impact to the project performance.

CONCLUSION

In this research, an example application with a case study of the Clinical Trials Programming is shown. And the objectives of this research which is to identify the key factor which occurs the reworks in the project using the System dynamics model and to confirm that System dynamics model contribute to oversight of the ongoing project from the perspective of project management were fulfilled.

System dynamics models have proven their values in contributing to not only simple but also complex development projects. And the examples of project managements applied System dynamics in business planning and developments or manufacturing settings have been seen many before. But the research focused on the way of oversight of a ongoing project with System dynamics has rarely seen. So, as the example application in this paper, System dynamics was applied to project management of Clinical Trials Programming.

Clinical Trials Programming is to generate statistical programming codes and the tables and figures as a part of the drug development activities in order to get approval for a new drug through submission to the each country authorities like FDA in US and PMDA in Japan. Because of the demands of high quality against the results which are generated from program codes, the results of ongoing outputs are reviewed and compared with correspondent outputs during this process. As a result of those ongoing Quality Control processes, some reworks were occurred. Those reworks in such a ongoing project will make troubles in the schedule, cost and manpower from a perspective of project management.

In this research, the System dynamics model for the Clinical Trials Programming was designed. It was based on the first rework cycle model and added flow of double programming. And also, the model was included ongoing quality check processes. As just described above, those ongoing quality check processes brings some reworks. And currently it is seemed that those reworks make problems over the programming process. Then this research tried to find the key factor which occurs the problems in this process.

To identifying the key factor which occurs problems in the process using the System dynamics model with sensitivity analysis was executed. As the results of the simulations using the System dynamics model of Clinical Trials Programming, the rework rate in the late stage of the process was identified as the key factor. The rework rate in the late stage of the process effects more sensitive to the total work volumes over the process than the one in the early stage. Therefore, if the rework rate in the late stage of the process is well managed, the total resources of the project will be controlled effectively.

As the conclusion, applying System dynamics to oversight of ongoing project is beneficial for project management of ongoing project. For example, it would be for not only Clinical Trials Programming but also most of ongoing projects. Because, to identify the key factor which occurs problem in the project using the System dynamics model, project manager could focus on the key factor which should be well controlled. In this research, System dynamics was applied to ongoing project management. And the key factor which occurs problem in the project was identified using the System dynamics model. Additionally, the contribution of System dynamics which is applied to oversight of the ongoing project were confirmed.

FUTHER RESEARCH

As the results of this research, it was cleared that the rework rate in the late stage of ongoing Clinical Trials Programming has stronger impact to the overall project performance than the rework rate in the early stage. Then, if project managers who has responsibility of those kind of ongoing projects want to improve the approach to their projects, they should take care about the rework rate in the late stage of those projects. However, to keep lower rework rate in the late stage of project, it is clear that the efforts in the early stage of the project are necessary. This point is not covered in this research. Then, the relationship between the efforts in the early stage and late stage have to be made clear in further researches.

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