

Research report: Playing NODEL - PCMG Annual Conference 2023

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Executive Summary

In June 2023 a team from The CURED Framework Ltd ran an interactive session at the PCMG Annual Assembly held in Mallorca Spain. In this session, delegates played NODEL, a simulation developed by the CURED team to help people involved in clinical research projects to better understand and manage the risks associated with the working relationship between clients (pharma) and contractors (CRO). Delegates played NODEL in teams, typically 6-8 people in each team, with teams made up of a mix of people working for pharma, CROs and other types of organisations involved in clinical research. Data were collected from the delegates who participated in the activity straight after the NODEL simulation had finished. The data were collected through a paper-based questionnaire which was designed and administered by academic researchers from Liverpool Business School, Liverpool John Moores University. The research was undertaken with the ethical approval of the university. In total 79 usable questionnaires were collected from participants.

Key findings from the research are:

- Overall satisfaction with the NODEL game and the NODEL trainers was very good and there was widespread agreement amongst participants that they would recommend the game to others
- Having played the game, the majority of participants had a better understanding of how relational risk can be mitigated in clinical trials through project management-related activities
- There was no difference in attitudes and opinions towards NODEL between participants working for pharma, CROs or other types of organisation, such as vendors, labs and consultancies
- A participant's understanding of relational risk significantly predicted work self-efficacy.
- A participant's feelings about cooperation in their work environment influences work self-efficacy

The last three findings suggest that playing NODEL, which enhances understanding of relational risk and feelings about cooperation, can play an important role in increasing an individual's work self-efficacy. This is particularly noteworthy, as work self-efficacy reflects a person's belief that they have the capacity to perform and deliver. The project management of clinical trials is more likely to be effective and efficient when individual's self-efficacy is high.

Background

The NODEL game is a tool used to develop awareness of, and provide solutions to, the problems associated with managing relational risk. Relational risk is about the problems that stem from unsatisfactory relationships between key stakeholders to outsourced projects, such as clients and contractors.

In the case of clinical research, key stakeholders are pharmaceutical (pharma) companies, who act as sponsors (client) and Clinical Research Organisations (CROs), who act as contractors.

NODEL was developed by The CURED Framework team to effectively manage the pharma/CRO relationship and, hence, help to successfully deliver clinical research projects.

NODEL is an interactive game which provides project teams with experience of implementing the principles and practices of CURED. CURED is a free Code of Practice published in partnership with the Institute of Clinical Research that de-risks clinical trials and improves performance, delivering positive outcomes for clients and contractors.

For more details of the CURED framework, see: <https://www.thecuredframework.com>

Purpose

The purpose of the research was to identify the extent to which the NODEL game is beneficial for staff involved in clinical research and effective in raising awareness of, and ways to manage, relational risk.

Research Methods

The NODEL game was played by delegates at the PCMG Annual Assembly in June 2023. After playing the game the research team obtained data from delegates, who completed a paper-based questionnaire straight after finishing the game.

Ethical approval for collecting the data was obtained from Liverpool John Moores University, the host academic institution of members of the research team.

The questionnaire consisted of five sections: 1) Participants' Organisation Details 2) Perceptions of Effectiveness of the NODEL Game 3) Aspects of Clinical Trials undertaken by Participants 4) Participants' Work Environment 4) Aspects of Participants' Future Work 5) a free text section for any addition comments participants may wish to make. Validated measurement scales used in previous studies and reported in existing academic literature were used where appropriate.

The section "Perceptions of Effectiveness of the NODEL Game" was made up of three scales. Q1 consisted of 6 questions, scored on a 5-point Likert scale, which asked participants to rate their satisfaction with the NODEL game and with the CURED trainers – 1 = Very Satisfied, 5 = Very Dissatisfied). The first item in Q1 was removed from the scale due to a lack of internal consistency, as measured by Cronbach's Alpha. Q2 asked whether the participant were likely to recommend NODEL to colleagues. This was done using a scale 0-10, where 0 = Not at all Likely to 10 = Extremely Likely. Q3, measured participants level of agreement with the following statement: "After the activity I am more able to understand how relational risk can be mitigated in clinical trials through project management-related activities". It was scored on a 5-point Likert scale of 1 = Strongly Agree to 5 through to 5 = Strongly Disagree.

The “Aspects of Clinical Trials undertaken by Participants” section (Question 4) asked participants to think about the relational risk in their current clinical trials. It consisted of 6 statements scored on the 5-point Level of Agreement Likert scale of 1 = Strongly Agree to 5 through to 5 = Strongly Disagree. For example, “My organisation is likely to think that other organisations will break promises”. The analysis required some adjustments to the statements to ensure internal consistency of the data.

“Participants’ Work Environment” focused on their tendency to co-operate with others in their work environments. This was scored using the 5-point Level of Agreement Likert scale. It asked participants to reflect on three areas: their beliefs (5 items), their behavioural tendencies (5 items), and their feelings (3 items). For example, participants were asked to rate how much they agree with the statement “I enjoy working with other project team members to achieve common success” (one of the items in the area of “feelings”. Overall, all scales were considered to have good internal consistency and hence were suitable for subsequent statistical analysis.

The section “Aspects of Participants’ Future Work” asked a question related to work self-efficacy, which was measured using an established work self-efficacy scale. This scale consisted of 10 items, scored on a 5-point Likert scale, where 1 = Not at All through to 5 = Very Well. For example, one item comprised of the statement: “Thinking of future work, how well can you collaborate with other colleagues”. The internal consistency of this scale was very good.

The questionnaire is provided in Appendix 1.

Results

In total 79 usable questionnaires were collected.

Participants’ organisations are shown in table 1 below.

Organisation	Number	Percentage
Pharma	28	35%
CRO	29	37%
Other	22	28%
TOTAL	79	100%

Table 1 – Participants’ organisations

Other types of organisations in which participants currently worked were: vendor/tech company (n=7), management consultancies (n=5), central laboratories (n=5), full service provider, academia, medical devices provider, software provider, decentralised service company.

Quantitative data

Overall satisfaction with the NODEL game was very good, with delegates generally satisfied (mean (m) = 1.99), with a similar score for the question, “I am satisfied with the NODEL game I participated in” (m = 2.06, standard deviation (SD)= 0.79). However, when asked to rate the overall usefulness of the game, scores were slightly lower and the results were more mixed (m = 2.46, SD = 2.72) (“The NODEL game activity was useful overall”).

Looking more specifically at satisfaction with the game, participants were very satisfied with the CURED trainers; “CURED trainers were knowledgeable” (m = 1.72, SD=.74), “CURED trainers responded promptly to people’s requests” (m = 1.86, SD= 0.79) and “CURED trainers were willing and capable to help people” (m = 1.68). In terms of the visual appearance of the NODEL game

delegates generally scored it high, although there were some responses that were less positive: “NODEL game materials were visually appealing” ($m = 2.27$, $SD=1.08$).

When asked if they would recommend the NODEL game to others, scores were generally good ($m=6.46$). Finally, participants generally agreed that after participating in the activity they were able to “understand how relational risk can be mitigated in clinical trials through project management-related activities” ($m=2.47$).

From the initial data analysis, several hypotheses were identified. These formed the basis of subsequent statistical analysis.

H1 there will be a difference in experiences of the game between delegates working for pharma, CRO and for other types of organisations.

To evaluate this hypothesis an ANOVA was conducted to test for differences between delegates type of organisation and 1) likeliness to recommend NODEL to colleagues, satisfaction with the NODEL game and relational risk understanding.

No differences were found between any of the variables. Therefore, H1 is rejected.

H2 the perceived effectiveness of the NODEL game will lead to an increase in relational risk understanding.

To evaluate this hypothesis, correlation analysis was conducted.

A statistically significant positive relationship was found between the two variables ($p<0.05$). This suggests that the more satisfied participants are with the game, the more they feel they have an enhanced understanding of relational risk, after the activity. Therefore, H2 is accepted.

H3 NODEL game recommendation to colleagues has a relationship with relational risk understanding.

To evaluate this hypothesis correlation analysis was conducted.

A statistically significant positive relationship was found between the two variables ($p<0.05$). This suggests the more likely participants are to recommend the game to others, the more they feel they have an enhanced understanding of relational risk, following the activity. Therefore, H3 is accepted.

H4 There will be a relationship between perceptions of relational risk in participant’s clinical trials and work self-efficacy.

To evaluate this hypothesis correlation analysis was initially conducted.

This found a statistically significant correlation between the variables ($p<0.01$) (items in Q4 and in Q6).

Simple linear regression was then used to test if perceptions of relational risk significantly predicted work self-efficacy.

The overall regression was statistically significant ($R^2 = .12$, $F(1, 71) = 9.67$, $p < 0.01$). It was found that perceptions of relational risk significantly predicted work self-efficacy ($\beta = .17$, $p < 0.01$). Therefore, H4 is accepted.

Three hypotheses focused on the relationships between a participant’s work environment and work self-efficacy.

H5a Beliefs around cooperation will influence your work self-efficacy.

H5b Behavioural tendencies around cooperation will influence your work self-efficacy.

H5c Feelings around cooperation will influence your work self-efficacy.

Correlation analysis was conducted, and no relationship was found between work self-efficacy and beliefs ($p=-.22$), behavioural tendencies ($p=-.19$) and cooperation. Hence H5a and H5b are rejected.

A statistically significant positive relationship was found between work self-efficacy and feelings of cooperation ($p<0.01$). Therefore, H5c is accepted.

Simple linear regression was then used to test if feelings of cooperation significantly predicted work self-efficacy. The overall regression was statistically significant ($R^2 = .12$, $F(1, 71) = 9.05$, $p < 0.01$). It was found that feelings of cooperation significantly predicted work self-efficacy ($\beta = -.11$, $p < 0.01$). Hence, H5c is accepted.

Qualitative data

The responses to free text section, asking for any addition comments participants wished to make, were analysed. (Appendix 2 provides all the responses.)

The data were coded into three high level themes, as shown in Figure 1 (see Appendix 1 for all responses).

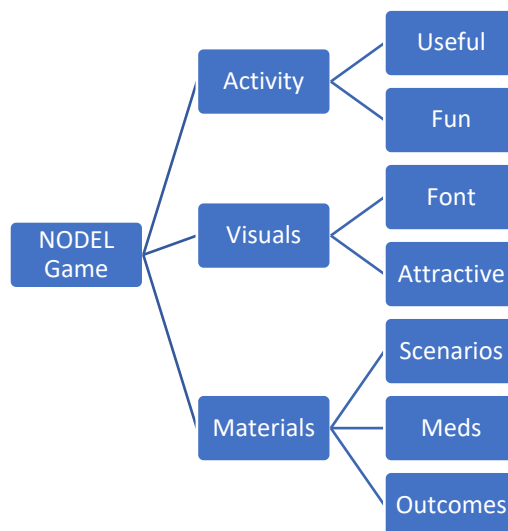


Figure 1: Thematic analysis of qualitative responses

Theme 1: Activity

Firstly, participants identified that the activity was a useful experience, one saying that it is a “terrific exercise”. They said it was useful, as it “... accommodates complexity of the CT process and acknowledges the difficulty of defining solutions”. One participant commented that “after playing the game I am more able to articulate the challenge”; suggesting that the NODEL game is useful to help players identify solutions to better manage relational risk in clinical trials. Participants also identified that it is a “fun” activity to participate in.

Theme 2: Visuals

Although participants did note the attractiveness of the game, saying that the “NODEL material looks good”, there was some criticisms regarding the font of the visuals. Feedback identified legibility of the font as an issue i.e., “... font is a little small”. In addition, there were comments regarding the colours used, “white font on yellow background” – which made letters hard to read. Therefore, it appears that whilst the visuals are attractive, in terms of the legibility and ease of use, the font and some aspects of the presentational material for NODEL could be improved.

Theme 3: Materials

There was feedback on three areas related to the training materials:

- 1) the scenarios,
- 2) the meds
- 3) and the outcomes.

One participant suggested that “Scenario #1 should be avoidable by basic oversight”. Therefore, this Scenario may need more explanation/elaboration to identify the difficulties associated with it and some of the complexity in terms of managing the relational risk.

In regard to the meds, there was feedback in regard to their descriptions (“Some of the Meds are very ambiguous”) and also of the number of meds (“Too many cards!”). The latter comment perhaps reflects the fact that the game was played over a relatively short period of time and at a fast pace. There was also feedback in relation to the outcomes. One participant stated that “there is no correct answer.” This suggests that in the setting up of the game, the scenario needs to be more clearly scoped/contextualised. In addition, a participant commented that the ‘correct’ meds should be identified through agreement, therefore this process could be explained more clearly in the rules of the game.

Sources of measurement scales

Pepe, Silvia J., et al. "Work Self-efficacy Scale and Search for Work Self-efficacy Scale: A validation study in Spanish and Italian cultural contexts." *Revista de Psicología del Trabajo y de las Organizaciones* 26.3 (2010): 201-210.

Lu, S., Au, W., Jiang, F., Xie, X., & Yam, P. (2013). Cooperativeness and competitiveness as two distinct constructs: Validating the Cooperative and Competitive Personality Scale in a social dilemma context. *International Journal of Psychology*, 48(6), 1135–1147.

APPENDIX 1 - Extract of the Survey

Your Organisation

Please indicate what type of organisation you work for as your primary employment (please select one):

Pharma

CRO

Other

If other, please specify

Effectiveness of the NODEL game

Q1: Please read the statements below and indicate your level of satisfaction with each.

Please score on a 1-5 scale with 1 being Very satisfied and 5 being Very dissatisfied.

	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
I am satisfied with the NODEL game I participated in.	1	2	3	4	5
NODEL game materials were visually appealing.	1	2	3	4	5
CURED trainers responded promptly to people's requests.	1	2	3	4	5
CURED trainers were willing and capable to help people.	1	2	3	4	5
CURED trainers were knowledgeable	1	2	3	4	5
The NODEL game activity was useful overall.	1	2	3	4	5

Q2: Considering your experience of playing NODEL, how likely are you to recommend this activity to colleagues? Please score on scale of 0 being not at all likely, to 10 being extremely likely.

Not at all likely
Extremely likely

0	1	2	3	4	5	6	7	8	9	10
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Q3: Please read the statement below and indicate your level of agreement with it.

Please score on a 1-5 scale with 1 being Strongly agree and 5 being Strongly disagree.

<i>After playing NODEL I am more able to</i>	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
Understand how relational risk can be mitigated in clinical trials through project management-related activities	1	2	3	4	5

Your Clinical Trial Projects

Q4: Thinking about a typical clinical trial project that you are currently involved in/will be involved with in the future, please indicate your level of agreement with the following statements. Please score on a scale of 1 = Strongly agree to 5 = Strongly disagree.

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
My organisation is likely to think that other organisations will break promises	1	2	3	4	5
We will be able to manage to get what we want, even when faced with objections from other organisations	1	2	3	4	5
My organisation is likely to think that the relationship with other organisations will deteriorate in the foreseeable future	1	2	3	4	5
My organisation is likely to think that other organisations will take advantage of us when the opportunity arises	1	2	3	4	5
We will be able to accomplish the assigned project tasks efficiently	1	2	3	4	5
We will be able to overcome any difficulties faced	1	2	3	4	5

Your work environment

Q5: Please read the statements below and indicate your level of agreement with each one. Please score on a scale of 1 = Strongly agree to 5 = Strongly disagree.

Beliefs	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
In order to succeed at work, a person must cooperate with their partners	1	2	3	4	5
I believe work performance could be benefitted more from cooperation than competition	1	2	3	4	5
I believe having a good partner at work enables you to triumph over all your opponents	1	2	3	4	5
A person must rely on the help of other project team members in order to achieve good results	1	2	3	4	5
Initiation and completion of any work is inseparable from the help and cooperation of team members	1	2	3	4	5

Behavioural tendencies	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
At work I would usually consider the interests of both parties	1	2	3	4	5
I can usually consider multiple views when I handle tasks	1	2	3	4	5
At work, I can usually stand in other team members' shoes to consider their interests	1	2	3	4	5

Behavioural tendencies (continued)	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
When working together with project team members, I am willing to listen to others' opinions often, even though I might not agree with them	1	2	3	4	5
When working with others on a communal task, I am able to integrate the views of others	1	2	3	4	5

Feelings	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
Working with project team members makes me happy	1	2	3	4	5
At work, I like collaborating with project team members	1	2	3	4	5
I enjoy working with other project team members to achieve common success	1	2	3	4	5

Your future work

Q6: Thinking of future work, how well can you... [please score on a scale of 1 = Not at all to 5 = Very well]

	Not at all	A little	To some extent	Rather well	Very well
Achieve goals that will be assigned	1	2	3	4	5
Respect schedules and working deadlines	1	2	3	4	5
Learn new working methods	1	2	3	4	5
Concentrate all energy on work	1	2	3	4	5
Finish assigned work	1	2	3	4	5
Collaborate with other colleagues	1	2	3	4	5
Work with people of diverse experiences and ages	1	2	3	4	5
Have good relationships with direct superiors	1	2	3	4	5
Behave in an efficacious way with clients	1	2	3	4	5
Work in a team	1	2	3	4	5

Further information/next steps

Q7: Please any additional comments you may wish to make in the box below.

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APPENDIX 2 – Qualitative data

High level theme	Sub-theme	Data (feedback from participants)
Activity	Useful	“Terrific exercise which accommodates complexity of the CT process and acknowledges the difficulty of defining solutions”
		“It does make you think and look back objectively”
		“Fully agree with CURED. Working in a good atmosphere impact on achieving positive results & project deliverance”
		“Thank you”
		“After playing the game I am more able to articulate the challenge”
	Fun	“And a lot of fun, which was essential after a long day of formal lectures/presentations”
Visuals	Font	“Font is a little small”
		“But [cards] are a little "style of substance" in terms of legibility (U=J!) and white font on yellow background”
		“Ditch the fancy font - C=C, U=J, R=R, E+E, D=J/C”
		“Suggest improving design of letter on the cards - perhaps instead of the current deign the rest of the letter could be "grayed out””?
		Attractive
Material	Scenarios	“Scenario #1 should be avoidable by basic oversight”
	Meds	“Some of the Meds are very ambiguous but...”
		“Remind teams to make a note of the meds selected for each scenario. So we can see during result reading””
		Too many cards!”
	Outcomes	“There is no correct answer”
		“The answers should be more of an average of responses from many different persons both CRO & Pharma”