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Perspectivas
Teóricas,
Metodológicas
e de
Investigação

Luis Fernando González-Beltrán
(organizador)



EDITORA
ARTEMIS
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Dados Internacionais de Catalogação na Publicação (CIP) (eDOC BRASIL, Belo Horizonte/MG)

H918 Humanidades e ciências sociais [livro eletrônico] : perspectivas teóricas, metodológicas e de investigação: vol. III / Organizador Luis Fernando González-Beltrán. – Curitiba, PR: Artemis, 2023.

Formato: PDF

Requisitos de sistema: Adobe Acrobat Reader

Modo de acesso: World Wide Web

Inclui bibliografia

Edição bilíngue

ISBN 978-65-81701-13-0

DOI 10.37572/EdArt_151223130

1. Ciências sociais. 2. Humanidades. I. González-Beltrán, Luis Fernando.

CDD 300.1

Elaborado por Maurício Amormino Júnior – CRB6/2422



PRÓLOGO

En este tercer volumen de Humanidades y Ciencias Sociales: Perspectiva teóricas, Metodológicas y de Investigación, seguimos en la línea de ofrecer trabajos de diferentes disciplinas que, desde sus propias trincheras, intentan el análisis de diferentes aspectos del ser humano, desde el enfoque en el propio individuo, hasta su contexto tanto inmediato como a gran escala, de la escuela que lo forma hasta la ciudad que lo cobija. Pretendiendo, como ya es usual, que el lector curioso encuentre en un solo lugar, lo que le llevaría una enorme labor en los buscadores de temas científicos. Sin perder el foco sobre lo que es inherente al humano, la variedad de autores, de metodologías, de idiomas, de países representados aquí, le dan un mayor valor a la síntesis que intentamos lograr.

La obra presenta 17 investigaciones agrupadas en 4 secciones: iniciamos con el tema A) Alumnos en su contexto escolar. La escuela tiene una importancia innegable en la socialización de los alumnos, por ello se tratan los distintos Procesos educativos, en sus diferentes entornos, tanto físicos como situacionales, así se analizan los problemas del trabajo infantil, los contextos rurales, la autorregulación en el aprendizaje, las habilidades intrapersonales, las competencias investigativas, el Aprendizaje Basado en Proyectos, el pensamiento crítico y alumnos con discapacidades. Es la sección que agrupa más capítulos, con 7.

Continuando con la escuela, vemos también la otra cara de la moneda, con el tema B) Docentes en formación, con dos estudios. También aquí vemos como los profesores se enfrentan a varios retos, por lo que aquí se trata la Planeación estratégica, la situación de docentes con estrés, su entrenamiento, y su ejecución cuando dedican su trabajo a los adultos, en situaciones de Formación a lo largo de la vida.

La tercera sección C) Empresas: Presente, pasado y futuro, revisa el siguiente contexto al que se enfrentan los estudiantes: el trabajo. Iniciamos con un vistazo al pasado, revisando la política de las empresas en el siglo de oro español; el presente con la internalización de empresas; y el futuro tratando cuestiones como, en primer lugar, los intangibles en la sociedad del conocimiento, y en segundo lugar, el diseño estratégico y la ejecución en manejo de proyectos a nivel empresarial.

Finalizamos con una sección D) Ciudades: Arquitectura, diseño, construcción y política. Un contexto físico macro, pero también un entorno Social y Cultural. Iniciamos con la utopía del momento, cómo diseñar ciudades verdes, la infraestructura para vivir bien. Seguimos con lo más concreto, tanto en términos verbales como en términos literales, cómo reforzar el concreto de los edificios que nos alojan. Le sigue otro tópico de urbanismo: recursos humanos en la construcción. Y para cerrar, un poco de política,

cómo en Europa se está manejando la Migración, la crisis de refugiados, un problema que se está agudizando en todos los continentes.

Intentamos haber representado lo más actual de las Humanidades y las Ciencias Sociales, y esperamos seguirlo haciendo en el futuro inmediato.

¡Les deseamos a todos una agradable lectura!

Luis Fernando González-Beltrán
Universidad Nacional Autónoma de México (UNAM)

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COMPLEXITY, DESIGN AND PROJECT COMPLETION: A STUDY OF CLINICAL TRIALS

Data de submissão: 25/11/2023

Data de aceite: 06/12/2023

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ABSTRACT: This study investigates design choices that determine project performance in a project management setting. Clinical trials are complex endeavors requiring contributions to and supervision of the clinical trial process. Each trial varies on several dimensions including the extent to which complexity plays a role in managing relationships with partners and overseeing distributed tasks related to clinical trial processes. Using data from 7648 Diabetes trials between the years of 1990 and 2023, I examine the effects of resource complexity, task breadth and resource applicability on the completion of clinical trials. The results show that resource complexity and task breadth increase the time to completion, whereas the availability of resources has the opposite effect. Partner complexity also contributes to increasing the time to completion. The implications of these findings for theories of coordination and

organizational design and management of distributed R&D work are discussed.

KEYWORDS: Project management. Organization design. Complexity. Coordination.

1 INTRODUCTION

Management scholars have analyzed the role of trust, competition, knowledge management, organizational structure, networks, experience and learning from partners as well communication problems as important determinants of coordination of activities across organizations (Ahuja, 2000; Gast et al., 2019; Gulati & Puranam, 2009; Gulati & Singh, 1998; Gulati & Westphal, 1999; Krishnan et al., 2006; Oliveira & Lumineau, 2017; Petersen, 2022; Srikanth & Puranam, 2014; Vanneste & Gulati, 2022; Vural, 2011; Zollo et al., 2002).

When competing in dynamic environments where technology can change rapidly, an important factor that determines firms' profitability and performance is the time it takes for firms to develop and commercialize their products (Chen & Hambrick, 1995; Chuang et al., 2022; Cohen et al., 1996; Cooper & Kleinschmidt, 1994; Lu et al., 2023; O'Mahony

& Karp, 2022). In settings where competition is based on technological supremacy and the underlying IP regime allows the firm to protect rents from its' intellectual assets for a pre-determined period of time, time to market is even more important (Cui et al., 2018; McCann & Bahl, 2017; Ranganathan et al., 2018) . Hence, speed to market becomes an issue of utmost importance for firms willing to benefit from their patented discoveries (Azoulay, 2004b).

However, there are substantial obstacles that firms have to overcome as they design and introduce new products based on their proprietary technology (McCann & Bahl, 2017). First of all, firms may not have the resources at their disposal to invest in the development of their technology into fully marketable products (Chaturvedi & Prescott, 2021; Karniouchina et al., 2022; Parmigiani et al., 2022), hence their in-house capabilities may be insufficient to carry out such a hefty process. Second, firms may not have the know-how associated with large-scale product development due to its age or industry related experience (Fang et al., 2021; Kimsey et al., 2023; Srinivasan et al., 2021; Wang & Chen, 2018). Third, external environment, including regulatory restrictions may deem it necessary for the firm to collaborate with outside partners when developing their new products (Wang et al., 2021). Taken together, these forces and factors require collaboration and coordination within and across organizations during the drug development and clinical approval process (Delerue & Sicotte, 2020).

Drug development process involves pre-clinical, clinical and post clinical (commercialization) stages (Azoulay, 2004b; Delerue & Sicotte, 2020; Lim et al., 2006; Pisano, 1996). Major part of pre-clinical work takes place in-house where biotechnology firms develop new molecules or biologics that can be potential candidates for therapeutic applications (Azoulay, 2004a; FDA, 2010; Huckman & Zinner, 2008). The clinical trials have three sequential phases each of which require increasing levels of time and resources but also are associated with increasing likelihood of successful product approval from the regulation authorities (Delerue & Sicotte, 2020; FDA, 2010). Biotechnology firms seek alliances with big pharmaceutical firms both for carrying out the clinical trials (Phase I,II,III) as well as large scale manufacturing and marketing of their drugs (Diestre & Rajagopalan, 2012). While previous research has investigated the importance of coordination of activities across bio-pharma partnerships (Diestre & Rajagopalan, 2012; Powell et al., 1996; Rothaermel & Boeker, 2008; Rothaermel & Deeds, 2006; Rothaermel & Hess, 2007), they have mainly focused on the choice of alliance partners, alliance formation and antecedents of innovation in collaborative relationships.

However, an important set of coordination activities that requires further attention takes place in the biopharmaceutical R&D process (Khanna et al., 2018) involving

clinical trial phases where designation of multiple sites for the study, involving various locations, a number of principal investigators as well as multiple participants is required (Azoulay, 2004a; Delerue & Sicotte, 2020; Huckman & Zinner, 2008; Khanna et al., 2018). Coordination problems with respect to this set of activities may create lags in product development which may eventually lead to incomplete termination of projects (Shepherd et al., 2014) resulting in a substantial amount of waste in terms of time and money.

Hence, this study explores project design choices and the extent to which complexities in task procedures determined by the nature of clinical study at hand effect the coordination of trials and timely completion of clinical studies. At the same time complexities stemming from the type of resource required and its utilization (Delerue & Sicotte, 2020; Khanna et al., 2018) as well as task characteristics that contribute to the rise of complexities in the distributed task environment are analyzed.

2 THEORY AND HYPOTHESES

Biopharmaceutical research and development process takes a substantial time to conduct (Pisano, 1996; Rothaermel & Thursby, 2007). While coordination and structuring of biopharmaceutical projects received attention in the literature (Azoulay, 2004b; Delerue & Sicotte, 2020; Diestre & Rajagopalan, 2012; Huckman & Zinner, 2008; Khanna et al., 2018), design of clinical trial projects and the interplay between coordination, complexity and performance in this setting has largely been overlooked with the exception of a few recent studies (Delerue & Sicotte, 2020; Shepherd et al., 2014). Clinical trials act as a setting that offers an excellent opportunity to study factors affecting management of complex projects (Delerue & Sicotte, 2020; Shepherd et al., 2014) that are distributed across multiple organizations (Huckman & Zinner, 2008). I use the clinical trial setting, to analyze the impact of resource complexity, task breadth, partner complexity and resource applicability on project performance. In order to do so, I use the data from diabetes studies that covers 33 years of clinical trial projects since the early days of research in diabetes area and gives a comprehensive picture of clinical development efforts across this domain. Observing the clinical trials that have been reported to the Federal Drug Administration database, the study draws a variety of variables to tease out the effects of design choices regarding task characteristics, resource complexity, task breadth and resource applicability while controlling for phases of clinical trials, types of study design and funding for the clinical trials.

2.1 RESOURCE COMPLEXITY AND COORDINATION

One of the factors that can create complexity in project work is the resource requirements that determine the extent to which a project can be completed in a timely manner (Delerue & Sicotte, 2020; Khanna et al., 2018; Shepherd et al., 2014). When resource requirements are high and they correspond to a higher degree of dispersion and coordination requirements across work tasks they result in complexities that may hinder project performance (Colicev et al., 2023; Oliveira & Lumineau, 2017). At the same time, the size of the tasks that need to be completed generally has a direct correlation with the resource requirements of an organizational project (Sihag & Rijdsdijk, 2019) and as such directly influences project outcomes (Espinosa et al., 2007). Although resource requirements in terms of the number of steps to be completed has been shown as an important factor determining the complexity in settings such as software development (Banker et al., 1998; Espinosa et al., 2007; O'Toole et al., 2023) and patent examination (Harhoff & Wagner, 2009), such complexity can have other attributes in different settings.

One such attribute is the enrollment requirements of clinical trials that stems from the need to test the procedures across a large number of eligible individuals. Interventions in a clinical trial include use of drugs, genes, vaccines and devices as ways of intervening with the state of health of volunteers under study (FDA, 2010) that need to be applied to enrolled individuals as designated by the study design. As the enrollment requirements in a clinical study increase, the resources demanded from the organization to effectively carry out the trial increases in tandem and the procedural complexity for carrying out the trial surges. One reason for this is the above-mentioned complexity associated with the procedural complexity; more individuals that have to be involved in the trial, the greater the site dispersion, the more coordination requiring knowledge of interventions, how these interventions should be carried out as well as the potential problems that may arise when implementing the interventions contemporaneously across a larger group of individuals. Concurrently, the protocols may require effective use of the limited organizational resources such as skilled personnel and investigators who have to coordinate action and distribute knowledge across a greater group of individuals. There may also be a temporal dimension that includes projects to simultaneously deploy resources for the larger group that is required by project design. There may also be complementarities across procedures which require special attention (Colicev et al., 2023), i.e. a drug that regulates insulin which should be applied while a high fiber, low calorie diet should be maintained and such attention is harder to obtain when the group in question is larger in size. In other words resource dependent complexity may not only

increase with task size but also with the amount of information and number and types of interrelationships between sub-processes related to the use of resources in carrying out the associated tasks (Delerue & Sicotte, 2020; Espinosa & Clark, 2014; Espinosa et al., 2007). This is similar to the concept of coordinative complexity discussed in literature (Wood, 1986). The increased level of resource complexity results in potential problems with regards to the management of clinical trials and negatively affects the timely completion of trials.

Hence, I hypothesize:

Hypothesis 1: The effect of the enrollment requirements as described by the number of subjects that need to be enrolled in a trial to complete the trial, on the timely completion of the clinical trial is negative.

2.2 TASK BREADTH AND VARIABILITY

Task breadth is another factor influencing the complexity of the task. The literature suggests that as the number of desired outcomes of a task increases, the associated complexity increases to the extent that the outcomes are not positively related with one another (Campbell, 1988; Colicev et al., 2023; Mishra et al., 2015). In the case of clinical trials, the number of conditions that are being addressed in the study can act as a proxy for task breadth. The conditions addressed in the study are the diseases and disorders for which the given treatment(s) are being tested (FDA, 2010).

An increase in the number of conditions not only increase the number of desired outcomes, i.e. task dimensions (Jiang & Chen, 2018; Klingebiel, 2022) that require attention but at the same it leads to higher complexity in understanding outcomes of the study because of the potential confounding effects of interrelations across conditions being addressed (Azoulay, 2004b; Delerue & Sicotte, 2020). There is a positive relationship between having an organizational focus on specific tasks at different levels and positive outcomes in terms of higher output and productivity (Huckman et al., 2009; Huckman & Zinner, 2008).

For the above-mentioned reasons, I expect a negative relationship to exist between task breadth and timely completion of a task.

Hence, I propose that:

Hypothesis 2: The effect of the number of conditions addressed in a clinical trial on the timely completion of the clinical trial is negative.

2.3 RESOURCE SCARCITY AND APPLICABILITY

Applicability of a given resource (Delerue & Sicotte, 2020; Hottenrott & Lopes-Bento, 2016; Mishra et al., 2015) in diverse settings and using different protocols is an attribute of the resource that generates flexibility and stems from the level of routinization of the underlying processes involved in the tasks (Cabral et al., 2020; Hinds & Kiesler, 2002). When resources can be readily available and easily deployed, the organization can more efficiently coordinate resource allocation in distributed work projects (Cabral et al., 2020; Rodríguez & Nieto, 2016). In comparison, when resources are harder to acquire from the environment and are scarce (Blau et al., 2004; Ferreira et al., 2022; Gong et al., 2021; Gueler & Schneider, 2021) in nature, the organization will not only need to outsource part of the efforts but also has to coordinate such dispersion. The difficulty that arises from searching for and acquiring critical resources that may be harder come by in a project setting may manifest itself negatively on the speed of task implementation.

In the clinical trial setting, one measure of resource applicability and scarcity is the extent to which studies can involve patients from diverse age groups (FDA, 2010). Studies that allow for a wider population range to be targeted by the treatment involve lesser degree of available routines for conducting the tasks as the tasks need to be adjusted to the different subject characteristics in relation to the subject's age. There are certain age groups, such as children or older adults who represent a lower percentage of the overall population and may be less inclined or likely to volunteer to take part in clinical trials. This increases the level of difficulty in carrying out the procedures and results in increased complexity of having to work across multiple sites to find the right type of subjects, all of which hinder the ability to complete the task on time.

Therefore, I hypothesize that:

Hypothesis 3: The effect of resource scarcity as shown by the age range of population that can be included in a clinical trial (children or older adults) on the timely completion of the clinical trial is negative.

2.4 PARTNER COMPLEXITY AND COORDINATION

Coordination of activities across organizations come with commensurate costs of delineating duties, delegating tasks, coordinating activities and sharing and communicating results as they happen (Castañer & Oliveira, 2020; Puranam & Srikanth, 2007; Reuer & Arino, 2007; Srikanth, 2010; Srikanth & Puranam, 2009). Organizations deal with the complexity of decomposing tasks among partners as they collaborate for R&D purposes (Gulati et al., 2009; Gulati & Singh, 1998), and such collaborations come with the

costs coordination that include monitoring and control of activities, joint search for paths to be taken as well as communication across departments and calibrating actions based on outcomes (Moreira et al., 2018; Oliveira & Lumineau, 2017).

As the number of organizations that have to jointly undertake tasks increases the requirement on communication of protocols, controlling of results and adaptation of work processes increases (Castañer & Oliveira, 2020). This is especially correct in settings where the coordination may involve a high degree of interdependence across tasks that need to be completed (Adler, 1995; Delerue & Sicotte, 2020; Gulati & Singh, 1998).

Clinical trials are carried out collaborating organization that coordinate their responses and make adjustments to the trial process on an ongoing basis as they receive information from the trial sites with regards to the performance of proposed treatments and as potential problems with the trial arise (FDA, 2010). The trial process may give rise to unexpected events such as adverse reactions that require adjustments to the protocol (Azoulay, 2004a; Delerue & Sicotte, 2020). As these adjustments require joint decision making across collaborators given the stakes of the entities in the results of the trial, the coordination requirements increase. The involvement of multiple collaborators increases the complexity and difficulty of coordination (Cabral et al., 2020; Castañer & Oliveira, 2020; Cummings & Kiesler, 2007; Hoang & Rothaermel, 2005; Moreira et al., 2018; Oliveira & Lumineau, 2017; Onal Vural et al., 2013) which in results in a negative impact on the timely completion of the clinical trial.

Therefore, I posit that:

Hypothesis 4: The effect of the number of collaborators in a clinical trial on the timely completion of the clinical trial is negative.

3 METHOD

3.1 SAMPLE AND DATA

For examining the effects of task complexity and coordination costs in a distributed task environment, I use clinical trials as a setting. Firms that wish to gain regulatory approval for market introduction of their drugs need to provide substantial evidence of their drug's effectiveness through controlled clinical trials (FDA, 2010). Clinical trials involve critical tasks such as recruitment of candidates, following up on the protocol set for study, submission of case reports including original patient records and charts (Azoulay, 2004a; Buonansegna et al., 2014; Delerue & Sicotte, 2020; Fogel, 2018). Clinical trials offer an ideal setting to study task complexity because tasks included in

clinical trials, vary by phase of the drug development process, the conditions addressed, the interventions at use and other trial specifications that determine the routine manipulation, storage and sharing of symbolic information within established categories (Azoulay, 2004a; Evens, 2016; Huckman & Zinner, 2008; Shih et al., 2018). At the same time, clinical trials also involve knowledge production which occurs through generation of search rules for identifying problems and heuristics that leads to their solution and which can't be reduced in simple protocol steps (Azoulay, 2004a; Huckman & Zinner, 2008). In this sense, each clinical trial displays a unique set of characteristics which reflects itself on the complexities of tasks involved in clinical research and the interdependencies between these tasks' attributes.

The sample to test the hypotheses consists of 7648 diabetes clinical trial observations between the years of 1990 and 2023. I have retrieved clinical trial data from the Federal Drug Administration's official website that includes data on all clinical trials associated with treatments seeking regulatory approval in the United States. Since United States is the main market for pharmaceutical companies, the FDA database which is the most comprehensive of its sort covers a significant portion of the universe of clinical studies carried across the globe. I have retrieved clinical study data by using relevant search words for identifying studies that are addressing Diabetes conditions and downloading all available information. After downloading the data, I have gone through clinical locations associated with the 7648 trials listed in final sample to correct for potential mistypes.

3.2 MEASURES

3.2.1 Dependent Variable

Trial Completion. The dependent variable project completion is the hazard rate that is built on the information of whether the event (trial completion) happened. The event is a binary variable that takes the value of 1 if the trial is completed and 0 if it is not and the trial duration variable time. The time variable is measured as the number of days from trial start date to trial completion (Delerue & Sicotte, 2020).

3.2.2 Independent variables

Resource Complexity. I have calculated the number of participants that a study is required to enroll as a measure of the level resource complexity involved in the study. As enrollment requirements increase in line with application of protocols and resource use and dispersion of project to multiple locations (FDA, 2010), they act as a good proxy for resource complexity in a given clinical trial project.

Task Breadth and Variability. I have calculated the number of conditions that are addressed in a clinical trial study in order to measure the breadth and variability of tasks that are involved in the study. Conditions addressed are disorders that are being addressed by the interventions in the study. The number of conditions addressed captures the breadth and variability of tasks involved since the conditions range from cardiovascular diseases to bone diseases, hypercholesterolemia, hypertension, obesity, kidney disorders, diabetic retinopathy and beyond. This variability in the targeted outcome measures of a study reflects itself on the procedures involved such as recruitment, application of treatment and analysis of results in addressing such diverse conditions (FDA, 2010).

Resource scarcity and applicability. I have utilized the age range determining the recruitment pool desired in a clinical trial study to measure the level of resource applicability and scarcity. Age range is an indicator of the variability in the population to which the task can be applied. I have created a measure that takes the value of 1 if clinical trial is only applicable to children and/or to older adults but not the wider population of adults as specified by the FDA (FDA, 2010).

Partner Complexity and Coordination. Using information from the content coding of sponsors collaborating in clinical trials, this variable refers to the total number of unique organizations/individuals that support the clinical trial. This variable captures the amount of coordination costs in terms of communication, information sharing and decision-making efforts across sponsors of a given clinical trial. It is similar in nature to the measure used to capture cross-institutional coordination in distributed work (Cummings & Kiesler, 2005, 2007; Kavusan & Frankort, 2019).

3.2.3 Control variables

Government Funded. The involvement of government organizations such as “National Eye Institute” or “National Institute for Diabetes and Kidney Disorders” is a factor that may influence the study completion time because these organizations have unique resources such as a grand database of patients registered through government agencies and expertise in conducting clinical trials in house. Hence, to control the effect of the involvement of such organizations, I have coded a dummy variable that takes the value of 1 if the trial is funded by a government entity and 0 otherwise.

Universities and Research Centers. Medical universities and the associated research centers conduct a significant part of their clinical trials in house and their studies are geared toward testing compounds from scientific discoveries for potential applications which creates a bias against clinical studies by these organizations with respect to the

studies conducted by pharmaceutical firms. To account for this, I introduce a dummy variable taking the value 1 if universities and research organizations are sponsoring the clinical trials and 0 otherwise.

Basic Science Based Studies. Studies designed to test the effect of an intervention based on discoveries of basic science in labs are involved with understanding the underlying mechanisms of the compounds and are not market oriented in nature. Hence, such studies may have a different time frame for application of the study. To account for the effect of such designs, a dummy variable is introduced. The variable takes the value of 1 if the study design involves basic science and 0 otherwise.

Treatment Based Studies. Studies designed to involve new treatments which may involve new approaches to surgery or new combinations of drugs rather than existing treatment modes with new compounds are controlled for by a dummy variable that takes the value of 1 if the study is a treatment-based study and 0 otherwise.

Randomized Studies. A randomized study is a study in which participants are randomly (i.e., by chance) assigned to one of two or more treatment arms of a clinical trial (FDA, 2010). Occasionally placebos are utilized. To account for the potential effects brought by the modes of conduct between randomized trials and non-randomized trials, a dummy variable is introduced taking the value of 1 if the trial is randomized and 0 otherwise.

Cross-over Assignment Studies. A cross-over assignment refers to the alternating assignment of subjects across placebo and treatment groups over the duration of the study. To control the effect of implementing this particular design on the timely completion of the given study, I include a dummy variable taking the value of 1 if the study includes a cross-over assignment design and 0 otherwise.

Studies Involving Multiple Phases. Several studies in the dataset have been designed to address two different phases at the same time. This increases the complexity of the study design, to account for the impact of having multiple phases in a study; I have created a dummy variable taking the value of 1 if the study involves multiple phases and 0 otherwise.

3.3 ANALYSIS

I tested my hypotheses regarding the effects of clinical trial project design characteristics on trial completion using survival analysis. In utilizing survival analysis, concerns regarding censoring were addressed in the set-up of the study and the analysis (Cox, 1972; Delerue & Sicotte, 2020). I employ Cox proportional hazard model using to estimate the effects of clinical trial design choices on the completion of clinical trials

(Belenzon et al., 2019; Cox, 1972). I also use OLS as a robustness check and control for the differences across phases and years of study, I receive similar results overall.

4 RESULTS

In Table 1, I report the descriptive statistics. Table 2 introduces the bivariate correlation matrix. In testing my hypotheses, I also included the variables stepwise to check and make sure that the signs of coefficients are stable across the regressions. If multicollinearity would have been a major issue, sign and coefficients could have changed direction. Taken together, these precautions minimized the problem of multicollinearity.

Table 1: Descriptive Statistics.

Variable	Mean	Std. Dev.	Min	Max
(1) Government funded	.05	.21	0	1
(2) Universities-Institutes	.46	.5	0	1
(3) Basic Science Studies	.06	.24	0	1
(4) Treatment Based Studies	.54	.5	0	1
(5) Randomized Studies	.76	.43	0	1
(6) Cross-over Studies	.14	.34	0	1
(7) Multi-phase Studies	.08	.27	0	1
(8) Resource Complexity	554.15	3773.69	0	100000
(9) Task Breadth	1.82	1.52	1	30
(10) Resource Applicability	.86	.34	0	1
(11) Partner Complexity	1.64	1.3	1	25

Table 2: Bivariate Correlation Matrix.

Variables	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
(1) Government funded	1.00										
(2) Universities-Institutes	0.10	1.00									
(3) Basic Science Studies	-0.02	0.05	1.00								
(4) Treatment Based Studies	-0.03	-0.17	-0.52	1.00							
(5) Randomized Studies	-0.06	-0.05	-0.01	0.03	1.00						
(6) Cross-over Studies	-0.06	-0.01	0.17	-0.11	0.14	1.00					
(7) Multi-phase Studies	0.04	0.11	0.01	-0.01	-0.06	-0.03	1.00				
(8) Resource Complexity	0.01	-0.05	-0.05	-0.02	0.06	-0.10	-0.04	1.00			
(9) Task Breadth	0.06	0.11	-0.02	-0.07	-0.01	-0.04	0.02	0.06	1.00		
(10) Resource Applicability	0.02	0.03	-0.11	0.10	0.00	-0.26	0.01	0.08	0.03	1.00	
(11) Partner Complexity	0.05	0.18	-0.01	-0.09	-0.00	-0.04	0.05	0.06	0.06	0.04	1.00

Table 3 shows the results of the survival analysis using different model specifications. Model 1 shows the baseline model which includes controls for involvement of government organizations in the study, inclusion of universities and research centers, study designs involving basic science, new treatments, randomized trials and cross-over assignments as well as a control for studies involving multiple phases. In Model 2, I introduce the first of my theory variables of interest (resource complexity). Model 3 includes the second theory variable (task breadth) and Model 4 includes (resource scarcity and applicability). Finally, in Model 5, I add the last theory variable of interest (partner complexity) with Model 6 including all variables of interest. Each model represents a significant improvement over the baseline model and the prior model with the log likelihood value increasing from -41497.04 for the base model ($p < .001$) to -41337.77 ($p < .001$) for the final model represented in Model 6 of Table 3. The baseline model was generally consistent with prior research findings for clinical trials. In line with previous research findings, the basic science based studies have a negative effect on the timely completion variable (Huckman & Zinner, 2008).

Table 3: Predicting Trial Termination: Cox Model Estimations.

	(1)	(2)	(3)	(4)	(5)	(6)
	Model1	Model2	Model3	Model4	Model5	Model6
Government funded	-0.52*** (0.07)	-0.52*** (0.07)	-0.50*** (0.07)	-0.51*** (0.07)	-0.51*** (0.07)	-0.49*** (0.07)
Universities-Institutes	-0.75*** (0.04)	-0.76*** (0.04)	-0.73*** (0.04)	-0.76*** (0.04)	-0.72*** (0.04)	-0.73*** (0.04)
Basic Science Studies	0.07 (0.10)	0.05 (0.10)	0.05 (0.10)	0.07 (0.10)	0.02 (0.09)	-0.01 (0.09)
Treatment Based Studies	0.21*** (0.05)	0.19*** (0.05)	0.18*** (0.05)	0.21*** (0.05)	0.15** (0.05)	0.11* (0.05)
Randomized Studies	0.18** (0.06)	0.20** (0.06)	0.19** (0.06)	0.19** (0.06)	0.19** (0.06)	0.22*** (0.06)
Cross-over Studies	0.85*** (0.05)	0.83*** (0.05)	0.85*** (0.05)	0.82*** (0.05)	0.85*** (0.05)	0.80*** (0.05)
Multi-phase studies	-0.08 (0.15)	-0.08 (0.15)	-0.05 (0.15)	0.03 (0.16)	-0.09 (0.15)	0.07 (0.17)
Resource Complexity		-0.00*** (0.00)				-0.00*** (0.00)
Task Breadth			-0.10*** (0.02)			-0.08*** (0.02)

Resource Applicability				-0.35***		-0.35***
				(0.05)		(0.05)
Partner Complexity				-0.19***		-0.19***
				(0.02)		(0.02)
Log Likelihood	-41497.04	-41470.40	-41474.01	-41463.52	-41410.28	-41337.77
Wald Chi-Square	1644.72	1653.72	1700.19	1684.93	1817.67	1913.66

Robust standard errors in parentheses, + p<0.1, * p<0.05, ** p<0.01, *** p<0.001, 7648 observations from 1990 to 2023. In all models, trial phase and trial start year is controlled for. A positive coefficient indicates a greater hazard of the event (trial completion) occurring.

Hypothesis 1: *Resource Complexity*. I predicted that the resource complexity as represented by the number of trial participants involved in a clinical study could have a negative effect on the timely completion of the clinical trial. Given Model 2's improvement over prior model, I inspect the coefficient of resource complexity variable which is significant and negative (the coefficient is significant; $b=-0.001$, $p<.001$). The result holds consistently in Model 6 with the coefficient equalling -0.001 , $p<.001$. This variable does indeed point to the negative effect of task complexity on timely completion supporting Hypothesis 1.

Hypothesis 2: *Task Breadth*. I predicted that the breadth of tasks involved in a clinical trial represented by the number of conditions addressed in a clinical trial will have a negative effect on the timely completion of the trial. In Model 3, the coefficient for task breadth variable was statistically significant. The main effect of the task breadth variable was negative ($b=-0.1$, $p<.001$), this effect remains significant throughout the rest of the models, and in the final model as well ($b=-0.08$, $p<.001$). This result supports my hypothesis: there are costs to having a wider breadth of tasks involved in a clinical trial process; the effect of number of conditions addressed on a clinical trial on the timely completion of the trial is negative.

Hypothesis 3: *Resource Scarcity*. I argued that the applicability of tasks as represented by the age range of subject pool desired for the study will have a negative effect on the timely completion of the study. Specifically, I have coded a dummy variable that takes the value of 1 if the subject pool is limited to children or older adults. Given Model 4's improvement over prior models, I inspect the coefficient of task applicability variable which is significant and negative (the coefficient is significant; $b=0.35$, $p<.001$). The result holds consistently with the coefficient equalling 0.35 , $p<.001$ in Model 6.

Hypothesis 4: *Partner Complexity*. I argued that the partner complexity and the associated costs of coordination as captured by the number of sponsors on a given trial will negatively affect the timely completion of the clinical trial. In Model 5, the coefficient

for partner complexity variable was statistically significant and negative ($b=-0.19$, $p<.001$). This result supports my hypothesis: there are costs to having more sponsors involved in clinical trial process which reflect itself negatively on the timely completion of the clinical trial.

5 DISCUSSION

The role of resource and partner complexity in distributed work processes is understudied, even though recent studies systematically document that geographical dispersion (Tzabbar & Vestal, 2015), team familiarity and task complexity effect the performance of distributed tasks such as software development (Espinosa et al., 2007; Knudsen & Srikanth, 2014; O'Toole et al., 2023; Srikanth, 2010; Srikanth & Puranam, 2014) as well as patent examination process (Harhoff & Wagner, 2009) and contractual alliances (White & Lui, 2005). The primary issue of concern in this study is to disentangle the effects of resource and partner complexity, task breadth and resource scarcity on the performance of project that includes distributed tasks such as those in clinical trials. This study documents how different task attributes create complexities which can hinder the performance a distributed work project and cause potential losses in terms of time and money. Below, I explain the implications of these findings.

First, I supply empirical evidence for the effects of resource complexity and its attendant coordination problems on project performance in clinical drug trials in diabetes. My primary contribution lies within the emphasis of complexity of clinical trial tasks in terms of resource requirements (Delerue & Sicotte, 2020). By analyzing the impact of resource complexity on project performance when tasks are interdependent, one can reach a more fine-grained understanding of under what conditions multiple tasks can be implemented without hindering project performance.

Second, I was able to analyze the effects of task breadth on the outcomes of distributed work in diabetes clinical trials. Having a wide arrange of conditions targeted in a clinical trial increases the costs of coordination as it increases the complexity and difficulty of communication, task allocation and effective management of distributed work projects (DiMasi, 2014; Evens, 2016; Fogel, 2018; Huckman & Zinner, 2008). It is harder for investigators to disentangle the effects of treatment outcomes. Increase in breadth widens task dimensions that require attention and at the same leads to higher complexity in understanding relationships across treatments, delaying project completion.

Third, resource scarcity and applicability was expected to have a negative impact on the timely completion of the project. Resource applicability may be inversely related

with availability of resources and the level of routinization of the underlying processes involved in the task. Tasks that are to be applied to a greater variability of settings need greater degree of manipulation to fit with the context and hence lose on the routinization and efficiency benefits that in implementation. However, results suggest the existence of a negative relationship between resource scarcity and project completion.

Finally, I find evidence for negative effects of partner complexity on project outcomes in terms of the timely completion of projects. My findings build up on previous literature and further tease out the effects of coordination problems that hamper collaborations in joint work efforts (Castañer & Oliveira, 2020; Cummings & Kiesler, 2005, 2007; Gulati & Singh, 1998; Khanna & Guler, 2022; Kiesler & Cummings, 2002; Vakili et al., 2022). Attending to such problems is important as the number of collaborations in sponsoring has increased steadily over the last decade, driven by several different motives including the need to collaborate and innovate in rapidly developing fields and the necessity to create more network oriented collaborative structures (Cui et al., 2018; Khanna & Guler, 2022; Natalicchio et al., 2017; Powell et al., 1996; Rothaermel & Boeker, 2008; Rothaermel & Deeds, 2006; Rothaermel & Hess, 2007). Given the results of this study, the partner complexity and associated coordination costs entail an issue of concern for organizations willing to jointly sponsor clinical trials.

5.1 LIMITATIONS

In spite of the study's contributions, limitations exist. I follow a reduced form approach to investigate the effects of resource and partner complexity, breadth and resource scarcity on the actual outcomes rather measuring directly intermediate processes and mechanisms. In this study, I measured resource complexity, task breadth and resource scarcity related to clinical trial tasks on the outcome of the clinical trial process, but due to data limitations, I could not have intermediate level data to actually measure the duration of task routines and problems that arise during clinical trial processes. Also, I do not have a control for the clinical site activity outside the diabetes research which may be influencing the outcomes of clinical trials in the dataset. Furthermore, my data is limited in terms of the observations reported to the clinicaltrials.gov platform. While I have employed robustness checks, utilizing different specifications and alternative approaches to analyzing the data using different methodologies, I have not been able to adapt more robust specifications due to the availability of resources. Studies building on this work can seek to incorporate third party data sources that collate more fine-grained data on firm and intervention details that may allow for better controls and more robust specifications.

6 CONCLUSION

Taken as a whole, the results provide evidence that different attributes of work design that impact resource complexity, scarcity, task breadth and partner complexity and the associated coordination problems as determinants of project performance in clinical trial projects (DiMasi, 2014; FDA, 2010; Fogel, 2018; Vural, 2014). Size and coordinative complexity of tasks increase the time to completion whereas availability and applicability of resources may be a potential precursor signalling faster completion times for projects that can avail of widely accessible resources. At the same time, having multiple collaborators increases coordination problems stemming from joint decision making, communication and problem-solving efforts and hampers the timely completion of clinical trials. More importantly, although much attention surrounds alliances in drug development, an issue that has been somewhat neglected was the coordination costs that constitute the downside of such collaboration. This study tried to disentangle the effects of task characteristics on the speed to completion of projects that are distributed across organizations. Further research should focus on the dynamic processes that are involved in the implementation of task characteristics by looking at intermediate level data that pertains to underlying mechanisms. Doing so, will bring a better understanding of not just the effect of task characteristics on project outcomes as was tackled in this paper, but further our understanding of how task characteristics may give rise to complexities at different stages of task related processes.

Overall, this study contributes to the theories of organizational design, complexity, coordination and project management. It helps disentangle the relationship between characteristics of project work in terms of breadth and complexity and the outcomes of distributed work. The study highlights the potential problems involved with tasks that involve processes which are interdependent, and which may interact to curb project performance.

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