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GUARDIANS OF INTEGRITY: ETHICAL IMPERATIVES IN THE FABRIC OF CLINICAL TRIAL CONTRACTING INDUSTRY STANDARDS

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Abstract
Clinical trials involve contractual agreements between multiple parties that govern the day-to-day interactions during the study. Ethical contracting is crucial to ensuring effective and mutually agreed-upon contractual agreements that protect the interests of all parties involved. The article proposes two ethical cross-check methods, the Virtuous Business Model and the Four-Way Test, to evaluate unknown factors such as patient safety and force majeure occurrences. The manuscript discusses the most important contractual components, including confidentiality, legal terms, and study-specific agreements. The document illustrates how evaluation of force majeure legal terms and patient safety risks is critical for ethical contracting. The article concludes that an ethical review of clinical trial contracts offers increased assurance to all parties involved, ensuring that all expectations are well-understood and unexpected risks and expenses are avoided.

Keywords: clinical trials, ethical contracting, contractual agreements, patient safety, force majeure

INTRODUCTION

Contracts are used extensively within clinical trials within the course of business. All parties —sites, sponsors, and CROs—see a minimum of three agreements per deal covering confidentiality, study responsibility, and account-level legal terms. There is a need for succinct language within each agreement that governs the day-to-day interactions. Most contractual reviews occur with a risk mitigation viewpoint. These crosschecks are a vital part of the risk mitigation necessary during the contractual review process. For the first time in most leaders' lives, the application of force majeure clauses related to wars and pandemics is now more likely to occur than seen historically.

Further, unique to the industry, contractual terms can be put on hold when patient safety is in mind. Accordingly, evaluating those two points (force majeure and patient safety) is critical, including revising the standard "boilerplate" language, which aligns with the ethical crosschecks. This article will outline successful techniques.

KEY CONTRACTUAL COMPONENTS

Contract Types and Requirements

There are multiple steps involved in developing and implementing a clinical trial contract. The first step requires the organizations to agree to the terms of confidentiality before sharing study-specific information. The primary purpose of this step is to protect intellectual property by promising not to steal each other's stuff or staff.

The next step is to agree on the legal terms that govern the agreements. This document restates confidentiality and adds data privacy, indemnification, regulatory, key contact information, and risk mitigation terms (Findlaw, 2018).

The last step includes the study-specific agreement. At its simplest, it outlines the fees, assumptions, timeline, and payment terms. It is possible to revise the study level agreement from time to time during the clinical trial as the study needs to adjust (e.g., regulatory feedback, expanded enrollment) through a change order (Binik-Thomas, 2022a & 2022b).

Considerations and Mutual Terms

Within the overarching agreements, confidentiality, and legal terms, it is crucial to contemplate two facets of fairness: mutually binding terms and neutrality. Mutually binding terms would include indemnification and confidentiality, while neutrality would consist of legal jurisdiction and cash flow. It is important to outline what is and is not covered under the study-specific agreement so that all parties understand expectations and avoid unexpected risks or expenses. Most contractual laws recognize there are inherent advantages to writing the contract. Any benefits derived from ambiguities in the language benefit the recipient.

Focus for Risk

Although risks are inherent in a contract and a clinical study, this article focuses on the carveouts related to patient safety and force majeure. According to Hack & Sackner (2017), patient safety is unique to the industry. It doesn't excuse sites or CROs from their contractual duties, even in blatant neglect or nonpayment situations or when patient safety is at risk, including study terminations and temporary stopwork notices. The contracting party needs to assess its risk proactively and address problems before they occur. Bowtie Risk Assessment (Attachment 1) can support this step. According to Barron (2010), a force majeure letter may be issued or received following the legal term agreement in certain situations, including accident, government act, emergency, pandemic, and war. Before governmental action on COVID, these clauses were often considered "noise," except for war zones; after the pandemic, each signatory's coverage has shifted front and center with financial and legal implications. A regulatory body may order a site shut down, but this does not relieve the practitioners from providing patient care equal to the current standard of care (e.g., it may exclude drugs under review). Hence the need for an ethical check at each junction. The Virtuous Business Model (Attachment 2) and the Four Way Test (Attachment 3) provide applicable and scalable assessments for this defined purpose.

ETHICAL SYSTEMS

Virtuous Business Model

The Virtuous Business Model proposes situations are approached and thought through using the "be, know, and do" process as a virtuous leader and a virtuous organization (Indiana Wesleyan University, 2016). It is essential to contemplate both realities for contract review, especially for the two key risks—force majeure and patient safety. On the organizational side, the economic capital component is particularly relevant. The signatory must ensure they act with principle, are proficient in the terms and conditions, and appreciate the profound risk. The responsible reviewers benefit from considering their professional capital. This crosscheck helps the reviewer manage the interaction with integrity. The

content is inspirational, making the world healthier and operated as inclusive as possible (FDA, 2020). For each trait, the relevant parties shall consider that they have covered the risks, sharing where possible while respecting the research basis and guarding the safety of the patients therein.

The Four-Way Test

The Four-Way Test contemplates four key questions: Is it the truth? Is it fair to all concerned? Does it build goodwill and better friendships? Will it benefit all concerned? The ethical crosscheck, developed by Rotary, has been adopted throughout many organizations, including the largest pharmacy chain in the

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United States (Walgreens,2019). The application is as straightforward in the contract as it is in day-to-day interactions. Each party must be respected—the signatories to the agreement, the financing group, the regulatory body/ies, and the patients. Each of them has overlapping responsibilities and co-equal concerns. In the end, though, a well-run trial helps improve the healthcare and, ideally, the quality of life for the patients. Even if the new medication is not efficacious for the enrolled patient, it may improve conditions for future subjects.

CONCLUSION

Clinical trials carry significant risks to all parties, and each organization strives to protect its interests within various contracts. In the past, a risk-mitigation review has been sufficient. Proactive analyses such as the Bowtie Model (Appendix 1) have been enough. However, new regulatory and governmental risk has expanded beyond any party's control in recent years. This force majeure situation is a governing agreement component that outlines risk-sharing elements. Even with COVID restrictions and war, the responsibility and obligation to care for patients remain, regardless of financial impact. An ethical review of the contract provides added assurances. The Virtuous Business Model (Appendix 2) and The Four-Way Test (Appendix 3) are exceptional frameworks.

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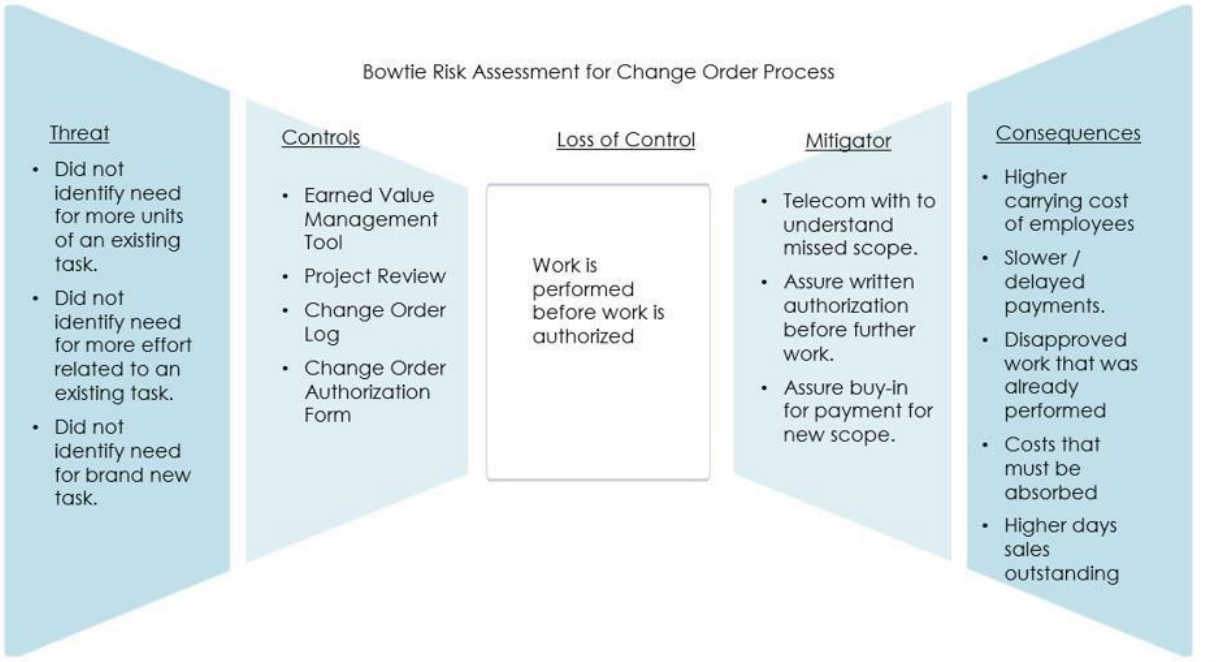
APPENDIX 1: BOWTIE RISK ASSESSMENT



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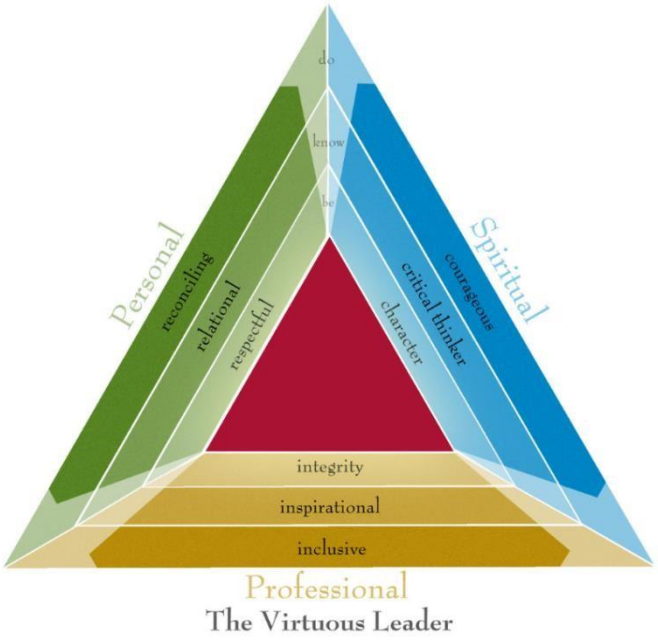
APPENDIX 2: VIRTUOUS BUSINESS MODEL



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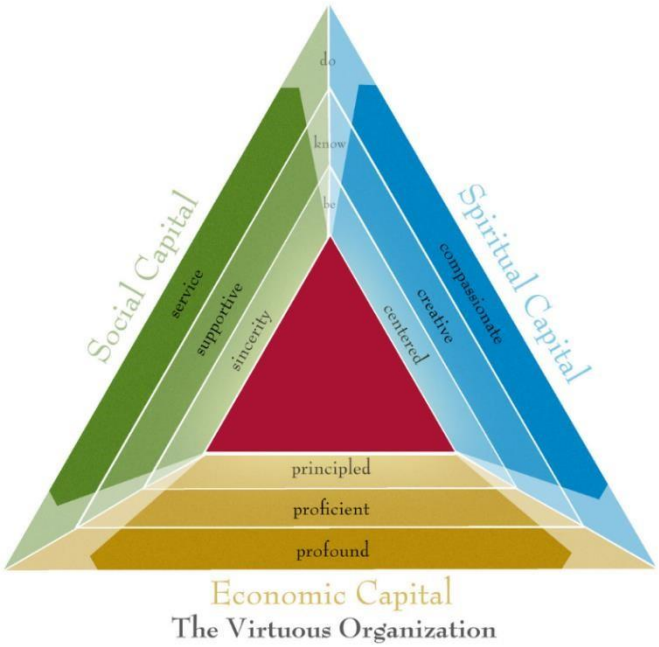
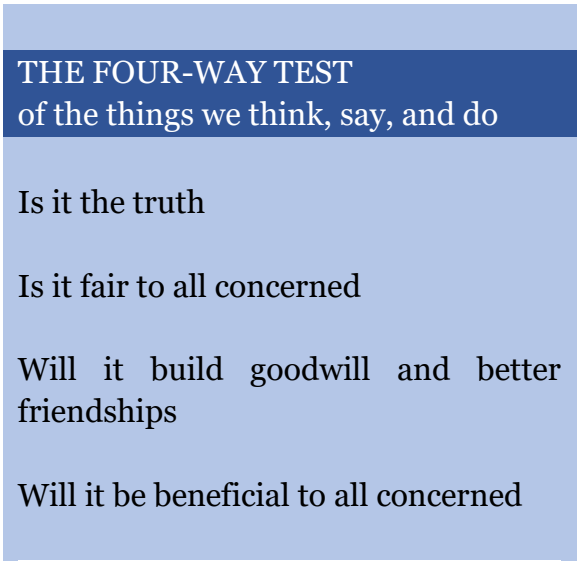


The virtuous business model with a blank center for secular use adapted from The *Virtuous Business Model,* DeVoe School of Business, 2022. Copyright 2016 by Indiana Wesleyan University. Adapted with permission.

APPENDIX 3: FOUR-WAY TEST



Rotary International developed the Four Way Test