

## **The CURED framework: an incremental innovation for managing relational risk in clinical research – Professor David Bryde (Liverpool John Moores University) and Roger Joby**

Projects are not only technical systems but also social ones and issues to do with both types of system cause uncertainty and risk when managing projects. Relational risk is about the high levels of uncertainty that are inherent in respect of the social system when a pharmaceutical company (Pharma), a clinical research organisation (CRO), and other sub-contractors and stakeholders come together to form a temporary coalition to deliver projects. The primary focus of relational risk management is on dealing with the potentially negative outcomes that arise from the high level of uncertainties around behaviours of the actors in the project coalition. This focus on managing the consequences of uncertainty around collaborative relationships does not replace traditional risk management; rather it is an enhancement of, and a complement to it.

A useful lens through which to view relational risk is agency theory. Agency theory explains how relationships work in situations where a Principal-Agent (P-A) relationship exists. A Principal (Pharma) engages an Agent (CRO) to undertake a service on their behalf, for example through the letting of a formal contract. In doing so the Principal delegates authority to the Agent to make decisions on their behalf. In addition, there are all the P-A relationships that exist between different firms in the supply chain. The presence of a dysfunctional P-A relationship can manifest itself in various ways, to the detriment of the project including; demonstrating opportunistic behaviour; acting in one's own best interest; disproportionately allocating risks or responsibilities and taking advantage of information asymmetries i.e. failing to share crucial information, including the concealment of negative outcomes. Such problems can hinder the functioning of the social system, leading to a lack of trust between the parties and can be a major source of relational risk. Focusing on understanding the sources of relational risk, such as agency problems present in P-A relationships, and then putting in place mitigation strategies to address them is a keyway of ensuring the social systems that exist in the project coalition operate effectively.

Therefore, a focus of attention in clinical research projects should be on ensuring the relationships are functioning effectively. This can be done in a variety of ways, including:

- Recognition of mutual benefits to achieve a win-win outcome and the sharing of risks, both threats and opportunities, with an open and transparent model of compensation
- Greater interdependence between parties, leading to collaborative working
- Bilateral or unified governance structures
- Development of a learning culture, including the sharing of explicit and tacit knowledge
- Investment in people including education, training and skills development.
- Rich interactions between the parties
- Fostering and recognition of the value of innovation, collaborative working, problem solving and creativity.

Utilising our findings from over 20 years of academic research, combined with more than 100 years of practical project management experience amongst our team, we have developed the CURED framework for managing relational risk. The framework has 5 elements which provides a focus for attention:

- Contract
- Understanding
- Resources
- Education
- Delegation

Within each element there are up to 9 capability nodes, which provide details of specific activities to undertake which will have a positive impact in terms of managing relational risk.

A positive advantage of utilising the CURED framework is that it involves small, relatively low risk, changes, which are consistent with the concept of incremental innovation. When people talk about innovation, they usually refer to disruptive, and often technology-based, kinds of innovations. However, this type of radical innovation accounts for less than 10% of commercial innovation. Most companies look to incremental innovation to stay competitive. Incremental innovation has a few features:

- It builds on existing knowledge and resources
- It is competence enhancing
- It involves relatively small changes
- It is easy to control
- It is low risk

This does not mean that the results cannot be dramatic. To give one example. Up to 2002 the British Cycling team had almost no record of success. British cycling had only won a single gold medal in its 76-year history. The new Head of British Cycling started preparing for the next Olympics and began to make small but measurable improvements. For example, they:

- Searched for small improvements in aerodynamic performance using wind tunnels.
- Made small changes to the environment in which they maintained bicycles, illuminating the role of dust and other impurities that impacted on the bicycles' performance.
- Hired medics to help athletes avoid illness
- Looked at diet and food preparation.

They searched for small improvement everywhere and found countless opportunities for such incremental innovations. When taken together, all these changes gave them a significant competitive advantage. At the 2008 Beijing Olympics, the squad won 7 out of 10 gold medals available in track cycling, a performance they matched at the London Olympics 4 years later.

The CURED Framework provides for such incremental innovation to take place in a project environment to deal with relational risk. Here is one example from each of the 5 elements of the framework:

1. **Contract** - The introduction of an early warning clause in the contract, through which all parties bring to the table anything that is likely to change the planned timeline, the cost or the quality of the project; hence combating, asymmetry of information etc.
2. **Understanding** -The differences in the business models between Pharma and CRO are recognised, leading to better communication, an increased likelihood of better decision making and more win-win solutions; hence combating conflict over company goals.
3. **Resource** – Development of a capability roadmap, combating a lack of trust on the part of the Pharma in the CRO's capability to deliver.
4. **Education** – Team behaviour training, increasing the awareness of relational risk amongst all parties.
5. **Delegation** - Providing an assurance strategy that allows the Pharma to delegate to the CRO without losing control and preventing the temptation to micromanage.

We can start the journey to improving the management of clinical research projects one step ahead of where the GB cycling team were in 2020 as the CURED Framework has already identified countless opportunities that are likely to lead to increased performance, and like the GB cycling team we have put in place the means to measure their effect. Because we are looking at an incremental innovation, the level of risk is low and the pace of change can be controlled, but the rewards can be significant.

For Further information about the CURED Framework please e-mail Roger Joby at [roger@1to1to1.com](mailto:roger@1to1to1.com)