

A code of practice
to aid successful
delivery of clinical
research projects.

Sponsored by



Forward

I am delighted to introduce the highly innovative CURED framework and code of practice. As Chairman of the ICR, one of the oldest membership bodies supporting and furthering the clinical research profession, I am excited to see how our industry will change through the application of this work.

The CURED Code that follows should be used as a guide to delivery that complements your organisation's processes. CURED is designed to improve the delivery of clinical trials to be more impactful than our current approaches, reduce delays, and most significantly, improve the relationships and well-being of all those participating in the research trials.

CURED aligns with the ICR's mission to improve standards and advance the profession. The CURED framework and code of practice emanate from the rigour and significant research that is the cornerstone of our professionals' daily lives. While our professional focus is always on furthering the quality of research, the CURED framework aims to improve outcomes through the optimisation of relationships and building delivery capability. It focuses on the way in which we deliver research. In the fast paced, post-COVID world, this is probably one of the most important issues we will need to manage.

I urge you to take this opportunity to drive your next generation of trials in clinical research using the CURED framework and code of practice.

Dr Alison Messom
Chairman
The Institute of Clinical Research



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Introduction

The CURED framework is a Code of Practice that has been developed to blend academic research with practical experience.

It represents a bold new move in delivering maturity and capability to better manage clinical trials that involve collaboration between a sponsor organisation and a Clinical Research Organisation (CRO).

CURED comprises five elements of capability (Contract, Understanding, Resources, Education and Delegation) that are each divided into Capability Meds. These Meds are informed by data-driven evidence Indicators (EIs). They range from commercial to behavioural and allow capability growth and financial benefits to be measured. As the framework is implemented, thought is needed on how these data indicators will be identified, collated and analysed. By monitoring and, where necessary, adapting to tangible outcomes, projects and organisations can apply conscious and continuous improvement.

CURED is based on structured empirical evidence that is backed by internationally-recognised academic research. It is aimed at both sponsor and CROs – from key decision-makers to clinical research assistants – in fact, anyone who has an interest in increasing the efficiency of the drug development process.

The framework tackles issues that are prevalent in the delivery of clinical trials. Indeed, the COVID-19 pandemic has truly highlighted the need to improve the process; to increase cycle times and maximise success rates. Now is the time to overcome these significant challenges. Now is the time to innovate.

Clinical research is defined as the process of testing drugs and treatments in humans and typically consists of four phases:

PHASE I

Initial testing on humans is relatively small scale, with between 20 and 100 healthy volunteers or patients. The key objectives are drug safety and efficacy.

PHASE II

This is a larger-scale clinical trial to test the drug in patients, typically 100-300 and often for the first time. The key objectives are also drug safety and efficacy.

PHASE III

This phase involves the drug or treatment being administered to patients, typically 300-3000, in the way it will be marketed. It is the final step that is needed to apply for a marketing licence and the key objectives are confirmation of safety and efficacy.

PHASE IV

This phase delivers post-marketing surveillance studies, where the key objective is safety.

A symbiotic approach of academic research and practical experience.



The benefit of reducing costs, cycle times, risks and issues is significant.

The need to effectively manage the relationship between a sponsor organisation and a Clinical Research Organisation (CRO) is increasingly recognised as being key to the successful delivery of clinical research projects.

More and more sponsors are outsourcing the clinical trial phase of the drug development process to CROs despite common issues such as:

- Oversight of CROs by project and clinical operations teams in sponsor organisations is mainly focused on risk mitigation and regulatory compliance
- Only 20% of sponsors that have used processes for CRO oversight for more than three years rate these processes as highly effective (Ref 1)
- Sponsors report mixed ratings of CRO effectiveness and typically do not involve them in upfront planning activities
- There are agency-related problems across all types of projects involving sponsor and CRO collaboration. This requires a focus on relational risk as well as traditional risk management.

There are calls for new business models to deliver complex projects, such as clinical research. These calls recognise that issues around poor project outcomes and dissatisfaction with current ways of working exist in the management of clinical research projects.

Historic data shows that 72% of studies were more than one month behind schedule, with such delays costing sponsors between \$600,000 and \$8 million for each day that a trial delays a product's development and launch (Ref 2). Phase II studies were behind schedule by 42% and although by Phase III this had improved to 30%, an average Phase III study completed more than six months late (Ref 3).

As there is almost zero evidence of any significant improvement in performance in recent years, this historic data probably remains an accurate reflection of the current situation. These statistics reflect the fact that outsourcing strategies and practices are often tactical and fragmented and hence do not always

lead to desired outcomes, with speed of delivery advantages reported by sponsors on some studies but not others.

The benefit of reducing costs, cycle times, risks and issues is significant.

Improving the clinical trial process holds the greatest promise for enhancing R&D efficiency in drug development. A 10% improvement in cycle time and success rates can save \$634m from the \$2.6bn average total capital cost of bringing a new drug to market – a saving of approximately 25%.

Part of the solution of realising such savings is through new ways of working in the delivery of clinical research projects. Recent research highlights the importance of having the right project management approach and building effective relationships (Ref 4).

This Code of Practice sets out a tailored project management approach for the delivery of clinical research projects to meet current challenges and resolve issues in order to maximise success. Specifically, it provides a consistent way to manage the relationship between the sponsor and the CRO, which is evidenced to be one of the largest contributing factors in project failure.

The CURED framework

The CURED framework, as shown in Figure 1, provides a structure to manage agency problems and mitigate relational risk. It has five elements that, when used together, set up a 'win-win' environment between sponsor and CRO:

CONTRACT – "contractual completeness" promotes shared expectations and goals between the sponsor and the CRO. This reduces the likelihood of destructive opportunistic behaviour by either party or of the CRO concealing issues that ultimately have negative consequences for the project. It also avoids excessive cost and unnecessary monitoring of the CRO's performance by the sponsor.

UNDERSTANDING – effective inter- and intra-organisation communication reduces information asymmetry and promotes a shared understanding of goals and risks.

RESOURCES – ensuring projects have the right people with the right capabilities at the right time in both sponsor organisation and CRO and retaining them as required during the project. This builds on the trust that has been previously established between sponsor and CRO.

EDUCATION – communicating the expectations of the sponsor to the CRO is critical for successful delivery. This needs to be supported by robust functional training programmes within the sponsor organisation for both hard and soft skills in project management competencies.

DELEGATION – the CRO is empowered when the sponsor can truly 'let go'. Trusting the CRO to deliver will create a flexible and more efficient relationship between the two parties.

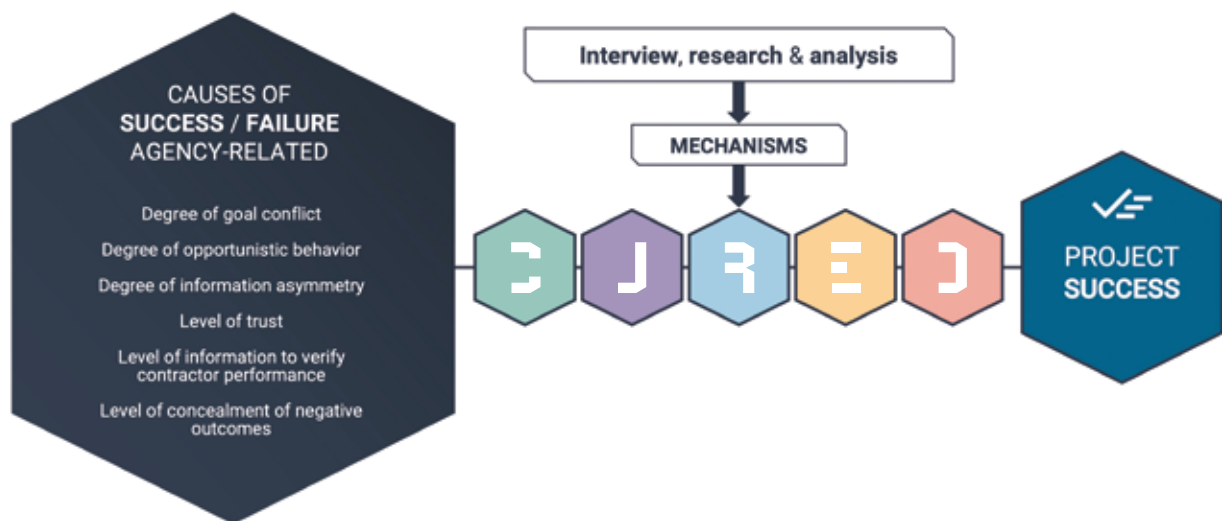
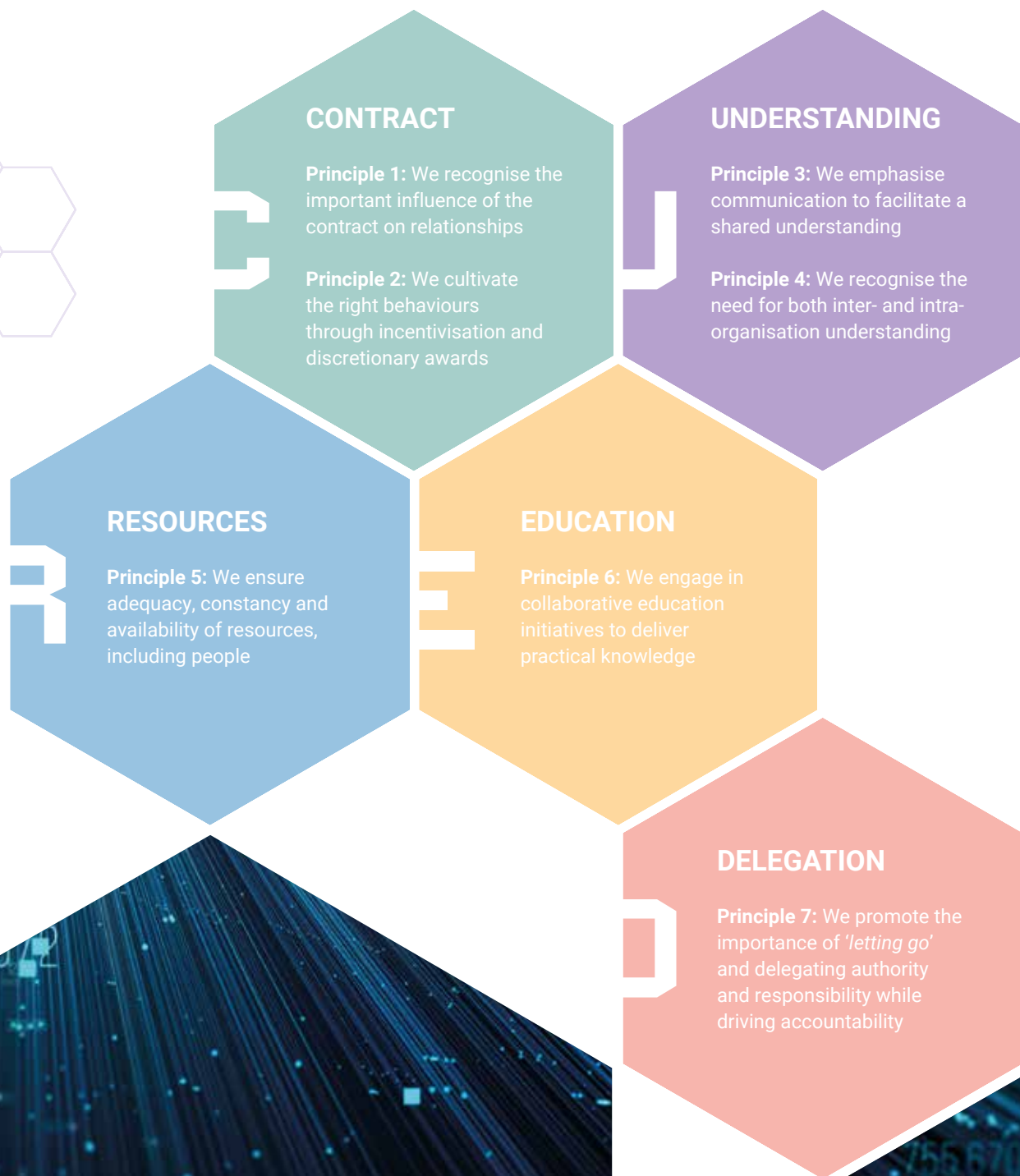


Figure 1.

The CURED framework for the successful delivery of clinical research projects.

Designed to set up a 'win-win' environment between sponsors & CROs.

The framework provides **guiding principles** to effectively manage the **relationship** between **sponsor** and **CRO**. These principles constitute the CURED manifesto for the **successful delivery** of clinical research projects.



Why CURED?

The CURED framework unites three key factors: **experience**, **research** and **lessons learned** from both **inside** and **outside** the field of clinical research.

It represents a bold new move in cultivating maturity and increasing capability to better manage clinical trials that involve collaboration between the sponsor and CRO. The genesis of CURED is in experience – we have immersed ourselves in the day-to-day problems that affect projects and programmes in clinical research and other project-intensive industries. Using decades of collective experience in multiple fields, we have identified the same systemic issues that are affecting projects.

The framework is based on academic research by the authors of this Code of Practice. This research was recently published in a leading peer review academic journal and a research report from the Association for Project Management (Ref's 5, 6).

This evidence base not only allows CURED clients and collaborators to accelerate learning, which is the cornerstone of successful contemporary businesses, but also to see their business adapt, evolve and realise more value. No longer relying purely on professional judgement and gut instinct, this is all about impact and certainty.

The subject of project management is highly codified (if a little fractured) and has no shortage of written guidance and training. As with other professions, it is facing unprecedented levels of complexity from all angles, such as:

- **increased regulation**
- **more complex protocols and therapies**
- **escalating costs**
- **governmental pressure on pricing**
- **skill shortages**
- **responding to pandemics and the unknown**

This ever-changing environment creates further challenges for the management of clinical research. With needs emerging from an uncertain financial and regulatory world and with increased political and social pressures, we can no longer simply rely on an established process to deliver change. Clinical research projects need to position themselves for success by using information, intelligence and the right behaviours to influence the best decisions. This can give a crucial edge in a highly competitive market.

The CURED framework can help design an operating model that delivers these enabling principles and provides a method of identifying the associated successful outcomes. It enables you to visualise your project management capability and the knowledge to translate its principles and methods. This will tangibly direct new ways of working and build capability in a way that makes sense for your business.

This framework represents a bold new move in cultivating maturity and increasing capability to better manage clinical trials that involve collaboration between the sponsor and CRO.

In short:

[Use knowledge to define where you want to be]

[Use evidence to see how you're doing]

[Adapt and change where you need to]

[Refine your understanding and continue your journey]

As you use this Code of Practice to embark on a transformational journey in the way you manage the collaborative relationship between sponsor and CRO, it is critical that you view individual failure in the delivery of specific clinical trials as a core part of success. No process or 'best practice' works perfectly the first time. It is far more valuable for an organisation to adapt to new understanding and ways of working in a phased approach – this is how we learn, change and evolve sustainably.

What is CURED?

The CURED framework is structured as follows:

1. There are five elements of capability:

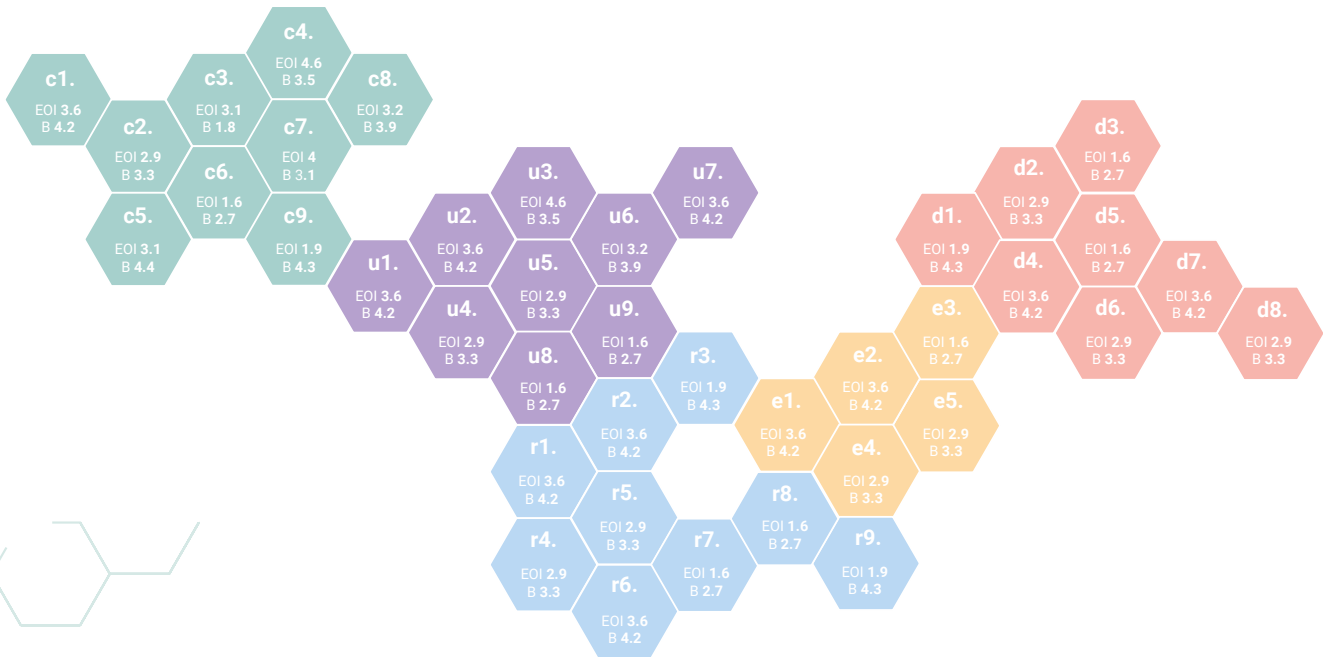


2. Each element has a set of up to nine Capability Meds that provide simple, clear and tangible goals that can be assessed, evidenced and assured. The diagram on the next page shows a complete listing of all the Capability Meds.
3. Each Capability Med is supported by a series of 'Med enablers' that have been analysed to define data-driven success indicators for all the capability improvement workstreams. Each enabler is weighted for ease of implementation and beneficial impact.

The organisational impact of each Capability Med is monitored at defined intervals to assess how much value each one is providing to your project(s) and therefore your business. It is this regular monitoring that allows a state of optimal performance to be reached through continual improvement.

The cumulative impact of these enablers drives the benefit that is achieved by each Med and, ultimately, the CURED framework itself.

The honeycomb



CONTRACT

- c1.** Contracting options selected to support achievement of project outcomes
- c2.** Project uncertainty assessed & risk appetite agreed
- c3.** Project complexity assessed
- c4.** Clearly defined project requirements set
- c5.** Project scope aligned to requirements
- c6.** Commercial incentivisation aligned to project goals
- c7.** Method of contract change agreed
- c8.** Behavioural Incentivisation & measurement agreed & in place
- c9.** Joint contract training undertaken with client & supplier

UNDERSTANDING

- u1.** Consensus that the Scope of Work delivers project requirements
- u2.** Project success criteria collaboratively developed & agreed
- u3.** Differences in the business models between the client & the supplier recognised
- u4.** Relevant method(s) of communication agreed
- u5.** Stakeholder engagement plan developed & agreed
- u6.** Project ways of working defined & agreed
- u7.** Vision, values & behaviours understood & aligned to project goals
- u8.** Partnering strategy in place
- u9.** Employee wellbeing strategy defined & measures implemented

RESOURCES

- r1.** Resourcing framework agreed
- r2.** Organisational capability assessment undertaken
- r3.** Organisation capability road map developed
- r4.** Internal & external resources identified
- r5.** Resource procurement method agreed
- r6.** Resource budgets developed
- r7.** Competency framework agreed
- r8.** Improvement plan developed and agreed
- r9.** Project team engagement and feedback processes agreed & in place

EDUCATION

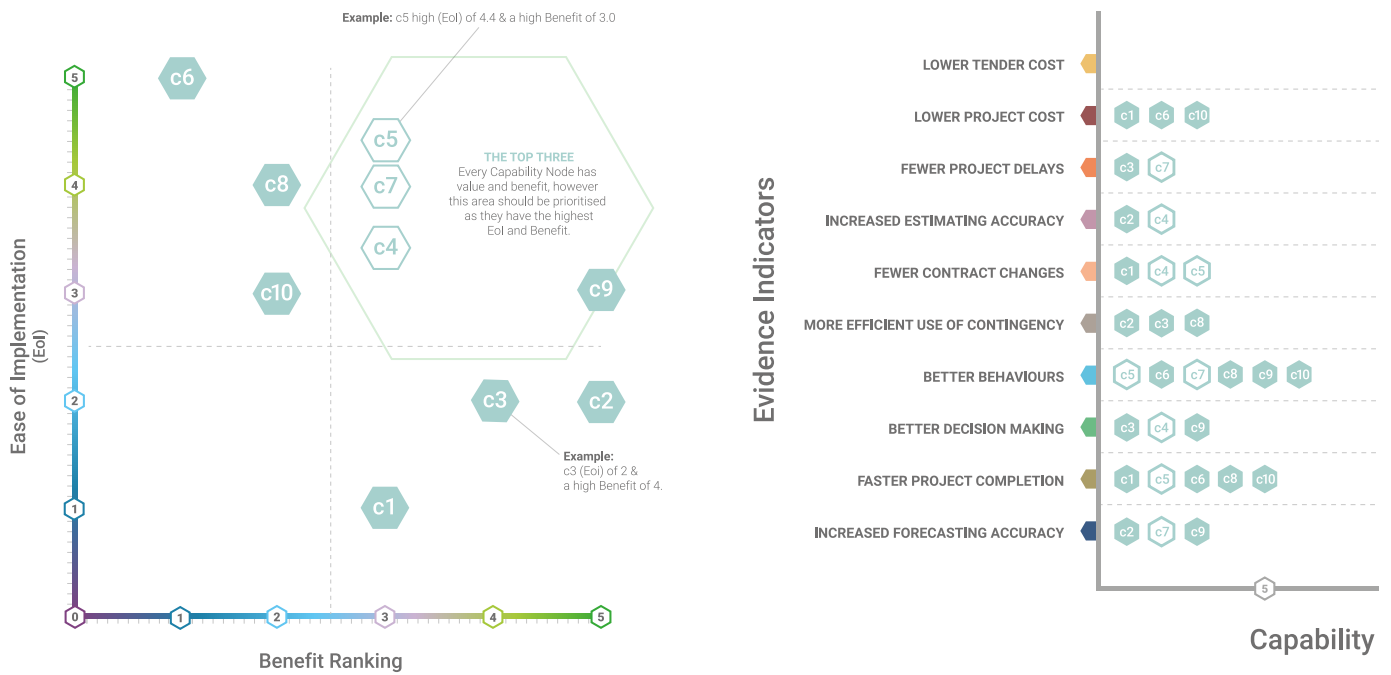
- e1.** Training programme developed (hard & soft skills in a compelling & engaging way)
- e2.** Education needs analysis (informed by stakeholder analysis)
- e3.** Knowledge sharing & management capability in place
- e4.** Staff & stakeholders are educated
- e5.** Team behavioural training complete

DELEGATION

- d1.** Leadership programme developed
- d2.** Project governance defined & aligned to organisational governance
- d3.** Levels of delegation set against risk & trust thresholds
- d4.** Area of expertise and control understood
- d5.** Roles & responsibilities clarified & agreed
- d6.** Decision-making processes optimised
- d7.** Level of autonomy set against organisational rules
- d8.** Assurance strategy defined & implemented

We have collaborated with industry experts in clinical research and with the sponsor of this Code of Practice, the Institute of Clinical Research (ICR), to develop tools to operationalise CURED. These tools will help you to optimise the way you grow delivery and organisational capability to deliver projects more efficiently. For more information about these tools and how to implement them, please speak with us.

The first tool is a capability heat-map that allows you to prioritise the embedment of CURED based on where your business is in its ability to adapt and change. E.g. If you can only do three things, then implement **c5**, **c7** and **c4**.



The success indicators from each Capability Med will guide you to tackle your own key issues and functional areas by providing data-driven evidence. This will de-risk change apathy and put your organisation on the most optimal growth curve. This will provide a way to measure the return on investment for business change and to prioritise efforts to sensibly get the quickest and most significant impact.

'The Top Three' represents the highest beneficial impact of each Capability Med combined with being the easiest to implement i.e. having the lowest operational impact.

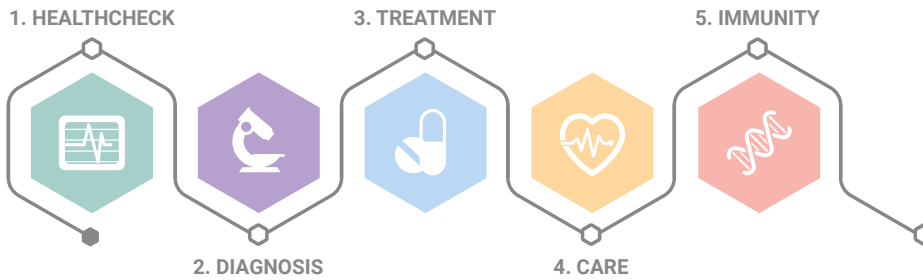
Visualising maturity

As part of CURED, we are developing secure contractual methods of sharing anonymised data from the framework's implementation and throughout its ongoing use. One of our key strengths is in expert research and analytical study. CURED uses a wealth of academic expertise combined with industry-leading analytics to deliver uncompromising insight and value to your projects. This data will provide the tangible evidence of your successful growth to build a sustainable culture of continuous improvement. It will allow you to evidence growth and to benchmark yourself against similar projects and organisations.

Sharing knowledge has been the catalyst for exponential growth in technology, and now we are applying these principles to deliver positive impact to clinical research. As part of CURED we have developed an implementation methodology that ensures maximum impact and benefit built around your individual needs and current maturity.

1. **HEALTHCHECK** - Where do you think you are? (Top Down)
2. **DIAGNOSIS** - Where are you? (Bottom Up)
3. **TREATMENT** - Where do you want to get to? CURED Configuration for maximum impact this defines your target capability
4. **CARE** - How are you doing with your capability growth efforts? Real time capability growth feedback
5. **IMMUNITY** - What are others doing and what should you do next? External benchmarking

Each step builds on the last to deliver tangible outputs that ensure you're in control of your maturity journey.





Social impact by design

CURED is more than just a tool to improve the end-to-end delivery of clinical and diagnostic trials for pharma. It is a dynamic tool informed by evolving data sets, maturing client capability and behaviours and society as a whole. CURED will have a wider impact than creating a more efficient delivery environment:

- Designed to support, improve and evolve outcomes for people, organisations and society in general
- Ensuring the workforce have a more positive experience at work, in the knowledge that they are valued, trusted & well at work
- Empowering leaders to lead from a credible evidence base and enabling trusted partnership between clients & CROs
- Expand, evolve & validate academic research, supporting academics & students alike
- Improve the lives & health outcomes of global communities by delivering clinical interventions efficiently, economically & effectively
- Helping big and small pharma to improve their approach to delivery. Enabling a better focus on clinical outcomes



Evolving project management practice

The approach will lead to Liverpool John Morres University (LJMU) adopting a research-informed approach to the development and delivery of project management curricula, incorporating leading-edge and innovative developments in the subject area.

CURED data will be analysed by academics, used as a basis for rigorous research, and play a major part in how we think about and evolve the practice of managing change.

As we then monitor the actual application of new knowledge, we create a virtuous cycle of positive, professional and social growth.





How to engage with CURED and the code of practice (cop)

CURED is flexible to the needs of trials and organisations. Each med should be understood in the context of your specific needs and governance. There is a 5 step process that will help your organisation get the most beneficial impact; however, at its most straightforward, the guidelines in CURED should be viewed as common sense operational adjustments to help build better teams and realise more success.

You can use the code as a standalone enhancement to help improve your organisation and / or projects. To do this you need to understand the outcomes of each element and Capability Med and translate your most important ones into tangible actions for internal change teams.

You can also engage our CURED champions to assess and analyse your current CURED capability and develop a roadmap of targeted improvements to get to where you want to be.

As CURED is a digital capability framework our CURED champions can also help configure our digital CURED dashboards to show you where you're improving and how it's benefiting your business.

Get in touch to learn more.

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www.thecuredframework.com

The Tangible Evidence Indicators

The framework has been developed to blend academic research with practical experience, in this sense it is critical that projects and organisations are able to evidence the successful application of the Capability Nodes and see tangible outcomes. This approach ensures that the framework is live and evolving as its application is tested and refined.

Success from tangible application of the framework manifests in several different ways we call Evidence Indicators (EI's). These range from commercial to behavioural but all can be measured to witness embedment, capability growth and financial return on investment.

As the framework is implemented, thought needs to be given to how data indicators will be identified, collated and analysed as this is the key to conscious, continuous improvement.

EVIDENCE INDICATORS

LOWER TENDER COST

LOWER PROJECT COST

FEWER PROJECT DELAYS

INCREASED ESTIMATING ACCURACY

FEWER CONTRACT CHANGES

MORE EFFICIENT USE OF CONTINGENCY

BETTER BEHAVIOURS

BETTER DECISION MAKING

FASTER PROJECT COMPLETION

INCREASED FORECASTING ACCURACY

C is for Contract.

The contract is often the most important yet overlooked part of the project. Many of the most high-profile project successes and failures have hinged on a client's ability to work clearly and collaboratively with a capable supply chain. Although, on the face of it, most of the innovation in managing projects has been in the use of data, there has been much to learn from the commercial and procurement space.

You will notice a definite theme across the outcomes in this section: clarity of accountability and an understanding of how the contract affects the relationship and roles of each party.

Clarity of accountability and an understanding of how the contract affects the relationship and roles of each party.

At inception, contracts are initially designed to be beneficial to the project. Over time, they can evolve to increase the mitigation of client risk by layering clause upon clause, which can increase complexity and reduce clarity.

Contrary to popular belief, *'being contractual'* can be a good thing if the contract is right for the job. It should provide a simple set of instructions and expectations from both parties and can significantly streamline the change process when used correctly.

It is reasonable to suggest that the scope and deliverables within the contract are explicit and that the process of managing commercial change is understood. Still, many types of contract don't suit clinical research projects.

Contrary to popular belief, *'being contractual'* can be a good thing if the contract is right for the job.

Under the microscope...

The themes behind the Contract element of CURED come from research and best practice, particularly in the areas of behaviour and collaboration. Modern contracts and clients are seeking ways to codify and manage these crucial aspects of a commercial partnership by:

- using New Engineering Contract (NEC) forms of contract, where positive behaviours are written into the contract itself; and
- increasing the use of collaboration – see ISO 44001 Collaborative business relationship management systems (formerly BS11000).

What can clinical research learn from other sectors in the preparation and use of the contract? How could these lessons be applied to deliver real benefit? To answer these questions, we must look at some of the critical issues that can be traced back to either incorrect contracts or the inappropriate use of them:

1. High levels of project uncertainty leading to project changes
2. Confusion over accountabilities
3. Increasing costs of contract administration
4. Outsourcing of contract management functions
5. Negative behaviours between sponsors and CROs
6. Lack of team cohesion

Although some of these issues seem normal in running a project, they can be significantly mitigated by applying some principles to the way you set up and run the commercial aspects.

Let's look at the links between the above problems.

We know through the study of principal-agent theory (see below) that there is a compelling link between the driving goals of an organisation and the culture of its people. On many occasions, there is a complete lack of appreciation for the core business drivers of partnering organisations. What can seem like inappropriate behaviours are simply the result of a different culture and perspective.

In any project, the sponsor aims to achieve business benefit by delivering the product it wants in the way it wants, and the supplier seeks to make money by doing what it's commercially obligated to do in a profitable way. Although overall success is preferable to everyone, they are measured differently by both parties: sponsor – product; supplier – profit. You can argue that reputation is a factor for both, but a supplier that favours reputation to the detriment of profit won't be in business long enough to realise its mistake.

Sponsors and CROs have different business models and goals. In an ideal world, the contract should promote the alignment of these goals or, at a minimum, it should promote a recognition of the difference and how it can be mitigated. For example, cash flow is often an important issue for a supplier, so the expedited payment of invoices is a positive way to recognise this difference.

By applying **c6, ('Commercial incentivisation aligned to project goals')** we can align the aims of both organisations. For example, the ultimate product of the research project is data related to drug safety and efficacy. If the contract has extra commercial incentives to hasten the receipt of clean data before the agreed contractual dates, then the sponsor can expect project decisions to always go in its favour as the CRO will be searching for ways to increase its profit through speed and efficiency. The fact that suppliers need to make money is frequently missed during the honeymoon period of the tender process. The transition from promise to execution can lead to mistrust and harmful tension.

Principal-agent theory defines the interaction between an agent and the principal for whom they act, when incentives are structured so that the agent will act to benefit the principal. The theory highlights issues that arise from the sponsor and CRO relationship, such as:

- **conflict over goals** (problems arising from different business models)
- **opportunistic behaviour** (decisions taken in the interest of individuals or an organisation that are contrary to the smooth running of the project)
- **information asymmetry** (the potential information gap between the sponsor that owns the data and the CRO that is collecting the data).

By applying the CURED framework, we can give both parties the best chance at working collaboratively to achieve project success, whatever that means to them.

CONTRACT - Capability Meds

c1 Contracting options selected to support achievement of project outcomes

There are many types of contract, which means that the sponsor and CRO will collaborate differently for each. If your project has high risk and high uncertainty, for example a pivotal phase II or III project, then it makes sense to choose a contract that promotes the capable adoption of change and a proactive approach to managing risk.

However, if cost is a driving factor, for example on a post-marketing study or a simple phase I study, then having increased specificity in the contract for deliverables and ways of working can limit financial exposure. This approach relies on the client knowing what it wants and giving clear and unambiguous instructions.

c2 Project uncertainty assessed and risk appetite agreed

Having a clear understanding of risk appetite is a fundamental part of setting up your commercial model. It should be based on the overall business risk appetite as well as that of the specific project. Sponsors with a mature risk management capability should take advantage of cost-efficiency by leading the identification and reduction of project risks. In practice, this means less reliance on transferring project risk into the supply chain, which will lower out-turn contract costs.

Where risk management capability is low or uncertainty around execution is high, contract options such as cost reimbursable with appropriate incentives should be used. This means both parties must have a practical and pragmatic approach to change, as this will be inevitable.

c3 Project complexity assessed

There has been much progress on the theory of project complexity over the last decade and it has rightly been identified as a key contributor to project failure. Ever-increasing structural, socio-political and emergent complexities bring increased risk to any project. Having a structured way to understand and evidence complexity is very beneficial and should be in place before starting the procurement process as it will significantly influence the contract type and level of supply chain capability required for successful delivery.

c4 Clearly defined project requirements set

Projects should undergo business benefits analysis prior to initiation. This process is usually completed as part of developing the business case. During this phase of the project, business drivers will be translated into project benefits, which in turn will be underpinned by specific requirements that will need to be delivered. The key deliverable for clinical research is clean data. The speed with which clean data is produced for pre-marketing studies should be of paramount importance since this will enable you to get the drug to market quicker. This will maximise the patent life or, alternatively, rapidly 'kill off' a non-commercial drug. However, these requirements are often not communicated to the delivery teams, which can lead to decisions being made that may ultimately hinder the overall success of a project and realisation of the benefits.

c5 Project scope aligned to requirements

In line with C4, once the requirements are set, sufficient time must be given to understanding and agreeing the project scope that will deliver those requirements. The more detailed the scope, the greater the opportunity for scope change. With less detail, however, there is increased delivery risk for the CRO. A scope based on deliverables as opposed to activities shares the risk more evenly and reduces the level of change orders. Scope change is a huge problem for clients and suppliers; it is the primary cause of delay in most projects. Every opportunity must be taken, where possible, to clearly define the scope of the project in both the tender and the contract. This will ensure a better cost estimate during the procurement phase, an increased understanding of supply chain capability, enable 'swift trust' to be built and a higher level of project certainty overall.

c6

Commercial incentivisation aligned to project goals

As previously stated, implementing commercial incentives can greatly enhance the probability of project success. Incentives should not be generic and should be collaboratively developed with the sponsor and CRO where possible. This will provide valuable insight into how the CRO can add real value during project delivery. Where this is not possible, using lessons learned from similar projects (both internal and external) can yield positive results.

c7

Method of contract change agreed

Without exception, change is indeed inevitable; every plan is simply an educated guess at a point in time and rarely has any project or undertaking gone precisely to that plan.

Given that change will happen, the solution is to have a structured way to understand the impact of it and then react accordingly. The early warning process in the NEC contracts, with its commitment to proactive risks analysis, is an excellent example of dealing with uncertainty in a collaborative way. Most change flows from CRO to sponsor, which puts the onus on the sponsor to administer project change collaboratively and capably. Having a good contractual change process and a back-to-back business process for this is essential.

c8

Behavioural incentivisation & measurement agreed and in place

Positive behaviours are key to project success. At every point in the project life-cycle, people will need to make vital decisions. A culture that emphasises relationships will help to ensure that these decisions are in the best interests of successful delivery. It will also increase morale, which further leads to increased productivity.

Measuring behaviours has become standard in many industries however the key is to commercially incentivise the desired behaviour. A culture of continuous improvement can be created by using KPIs to reinforce positive action.

c9

Joint contract training undertaken with sponsor and CRO

The contract is the core of the sponsor/ CRO relationship. It sets the context for every decision made during the project. Yet most contracts are worded in a convoluted and sometimes subjective language, and the number of teams that read and understand the contract is low. Having a clear and shared understanding on process and accountabilities between parties will significantly increase the efficiency of contract administration and the project itself.

There are many providers of contract training, so it is essential that your specific contract is turned into a viable training course that is delivered not just at the start but also during the project when human resource may change.





By applying c6, we can align the aims of both organisations. For example, the ultimate product of the research project is data related to drug safety and efficacy.

J is for Understanding.

Understanding is something that we generally take for granted. Our perspective is shaped by experiences and knowledge, but it is also affected by our mental state, morals, ethics and environment.

Sponsors and CROs have different business models; sponsors are interested in the development of sales and marketing; CROs sell expertise and time for a specific clinical trial or programme. In an ideal world, we would align organisational goals to achieve maximum success. As this is often not possible, an understanding of each organisation's key drivers can help to overcome invisible barriers that would otherwise exist.

Understanding your partner's needs and helping them to achieve their goals can be easier than it sounds. It is sometimes difficult to align organisations with different business models, but accommodation is always possible. An example of this is recognising the importance of cash flow for your suppliers and timely completion of deliverables for the sponsor.

This message of accommodation is also relevant at departmental, team and individual levels. The unique perspectives and motivations of different stakeholders can influence and affect your study.





| Understanding is different for different people.

Testing the theory...

In this section, understanding is not training; it is critical knowledge, where the right people know the correct and best course of action at the right time.

It is about providing enough contextual intelligence for your team to instinctively know how to tackle change and adversity, deliver a complex study, or champion autonomy to de-risk the adverse effects of change.

By accepting the following points, the importance of tangible ways to maximise common understanding becomes apparent:

- **that understanding is different for different people**
- **that collaboration and coordination need a common set of goals and the ability to adapt to unexpected or uncertain situations, whilst still achieving those goals.**



Let us take u3 as an example:

u3 - Differences in the business models between the client and the supplier recognised.

Our research into principal-agent theory tells us that people are driven by their own needs and agendas. In our studies of numerous projects, the successful ones had built-in shared goals tied to positive results. Indeed, there were significant structural differences between the successful projects but, due to a common platform of understanding, they achieved similar success.

One of the successful projects was a global non-small cell lung cancer study. Like all projects there were problems to be solved but the two key personnel – the project manager (PM) from the CRO and the pharma PM responsible for oversight – had a clear understanding of the different pressures that they had to deal with. This was partly due to their experience and the excellent relationship that they had. Understanding each other's issues led to an environment that facilitated win-win decision making. A repeat study with different PMs was far less successful because of this lack of understanding.

Culture plays a major part, and every organisation has its own. Many businesses are driven by financial motivation; you would expect that rewarding the right actions with financial incentives would deliver results – however, relying exclusively on such incentives is not the best approach. In our research of successful projects, consideration was given to the needs of all parties involved, which included non-financial incentives as well as financial ones.

Clearly, understanding is an essential element that should not be overlooked. By understanding each other's perspectives, goal conflict, which can be highly destructive to effective working relationships and therefore a major threat to achieving positive project outcomes, can be minimised. Hence different perspectives are respected and aligned to achieving the project goal.

Sharing a common perspective is one of the ways to increase project success. It is crucial to realise that understanding is a holistic enabler that transcends pure knowledge, which is often in plentiful supply. The goal should be to give enough context that your team, no matter what level of knowledge or expertise it has, makes decisions that are in the best interests of the project. This will become increasingly important as society and markets move towards more complex delivery environments, and when agile becomes a true necessity rather than just a buzz word.

Understanding your partner's needs and helping them to achieve their goals can be easier than it sounds.

UNDERSTANDING - Capability Meds

u1

Consensus that the scope of work delivers project requirements

All projects should have a business case on which they are assessed, selected and authorised – it justifies the project's existence. It should clearly articulate the requirements that the project needs to achieve. Although this seems obvious, most projects struggle to link the requirements to the detailed specification on which the scope and execution strategy will be based. Aligning these at the start of the project is essential.

u2

Project success criteria collaboratively developed and agreed

Having tangible success criteria is fundamental to any project. While a good sponsor avoids ambiguity by communicating what project success looks like from the outset, it must be recognised that success may change as projects and environments change. Regular review points therefore should be planned throughout the project.

In an evolving landscape where innovation is more prevalent now than ever, success has matured beyond binary measures. A collaborative approach to understanding and defining success will help you to realise early opportunities, de-risk potential delays and increase benefits.

u3

Difference in the business models between the client and the supplier recognised

As highlighted in the introduction, understanding the criteria for the business models of a project's key parties and stakeholders is critical to achieving success. A valuable insight into the drivers behind key decisions and motivations will, in turn, allow the project team to anticipate and take action to avoid situations that may have a negative impact on the project.

This understanding of each other's perspective will also encourage empathy. This helps to maintain a strong positive relationship between the different organisations of the project and is a major contributing factor to successful projects.

u4

Relevant method(s) of communication agreed

Communication, or lack of, has been cited as one of the most common causes of project failure. Whenever possible, projects should focus on an evidence-based approach to communication and its impact. Having data indicators for levels of positive engagement will help ensure your communications are effective. For example, The Barcelona Declaration of Research Principles was the first overarching framework for effective public relations and communication measurement. Using a framework such as this will significantly increase a project's ability to understand its communications impact by showing its ability to reach the right audience with the right messages.

Approaches that can be evidenced are central to the CURED framework. An area as vital as communications should form a key part of the project strategy and organisational capability.

u5

Stakeholder engagement plan developed and agreed

You should never underestimate how stakeholders can influence project delivery. A stakeholder management plan has been a core deliverable in project management for many years. It is essential to note that as your project and the environment in which it is delivered change, so do your stakeholders. Collaboratively identifying and mapping out your stakeholders throughout the life of the project is fundamental. Seeing stakeholder engagement and management as an organic process that is maintained and relevant is where real value can be realised, and finding opportunities to involve rather than manage stakeholders can bring positive outcomes. Attention should also be paid to regional requirements.

U6

Project ways of working defined and agreed

Most of the ways of working that are relevant to the sponsoring organisation will not achieve the best results if applied to the CRO. A project should be thought of as a unique organisation with its own operating model and with processes that include all of the parties involved.

A balance of clear and concise ways of working that unifies the collaborative goals between sponsor and CRO is key. Ensuring compliance with corporate processes and legislation is only one element, and this is an area where innovation can deliver new value and increase efficiency and effectiveness.

U7

Vision, values and behaviours understood and aligned to project goals

Working as one team is an obvious aspiration for most projects, however, not enough effort is given to developing and codifying a genuinely integrated and collaborative delivery approach. Integrated project delivery (IPD) is a project delivery model built around a collaborative alliance of stakeholders who each share risk and reward. Using the IPD model is a robust way to understand strengths and to use functional and departmental interfaces to realise an efficient delivery organisation. Comprehensive training for the entire team in the way it should work together is equally as necessary; it makes the difference between well-designed aspiration and reality.

U8

Partnering strategy in place

Partnering strategies are predominantly commercial undertakings and the core business drivers for each organisation are often different. While a business may define where it needs to outsource, such as areas that lack expertise or resource or make financial sense to undertake, this is usually a desktop exercise that ultimately informs a procurement strategy.

Each organisation involved in the project must fully understand what the other brings. Is it innovation? Compliance? Or specialist skills? Knowing and, more importantly, valuing each part of the team is a key factor in working usefully and efficiently as a unit. By promoting an awareness and appreciation of each other's skill sets, both morale and efficiency will increase.

U9

Employee wellbeing strategy defined, and measures implemented

One of the most significant breakthroughs in recent years is the advent of new ways to engage employees and consider their wellbeing, both from a mental health perspective as well as health and safety. Projects are tough places to work, and employee burn-out and churn is a key business and project risk. Many forward-thinking organisations have wellbeing strategies that mitigate stress, absence and significantly increase morale, efficiency and positive autonomy.

Much thought should be given to maintaining a positive environment to support the project team as it overcomes adversity and change. Defining data indicators to assess wellbeing is critical.





The goal should be to give enough context that the team, no matter what level of information it has, makes decisions that are in the best interests of the project.

In our studies of numerous projects, the successful ones had built-in shared goals tied to positive results. Indeed, there were significant structural differences between the successful projects but, due to a common platform of understanding, they achieved similar success.

R is for Resource.

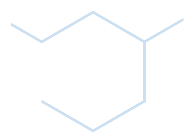
Even if you are the head of a pharma company or CRO and have the ability to clone yourself, you still would not have the breadth of skills required to deliver the projects that your business depends on for survival. You inevitably need other resources to deliver them, but it is becoming increasingly difficult to find the right people with the range of skills required at the right time.

A recent trend, agile project management is an approach to enable your team to work in a more dynamic way. This new way of planning and managing project resources and focusing them on beneficial goals has brought new expectations to senior managers and stakeholders. However, an issue that has always bubbled under the surface of any project is now a stark reality; there are not enough people to do the work we need, when we need it.

Lack of skilled resources ranks as one of the most common corporate risks; almost every business is looking for ways to mitigate the impact of this global issue. Resource isn't only about quantity, quality and availability though – given the right leadership, training and motivation, every person within an organisation is a valuable resource that can make the difference when faced with complex challenges.



With the psychological landscape of work and life changing more rapidly than ever before, continuous engagement is essential.



Tools of the trade...

There are many tools and techniques available to plan and forecast resource demands. If we take the technical aspects of managing resources as a given, then capability comes to the forefront. It is here that the focus of CURED is most visible.

New ways to classify and influence people's behaviours have changed modern business. Senior management is routinely assessed and analysed for traits that complement strategic aims, and behavioural training is a proven fundamental part of project and commercial success. Employee interaction is no longer only a performance review at the end of the year. With the psychological landscape of work and life changing more rapidly than ever before, continuous engagement is essential.

Understanding your people and the skills of the wider team is a vital part of building the right project delivery team. Behavioural science is continually evolving and has shown us what motivates people and how they best respond to adversity and challenges. Our research shows that the impact of conscious and unconscious motivators on a team leads to project success.

Bringing the right blend of people and personalities into a supportive environment that meets their needs will give you the advantage when you need it.

It is becoming increasingly difficult to find the right people with the range of skills required at the right time.



The procurement of resources, both internally and from suppliers, is a more mechanical but no less important part of this process.

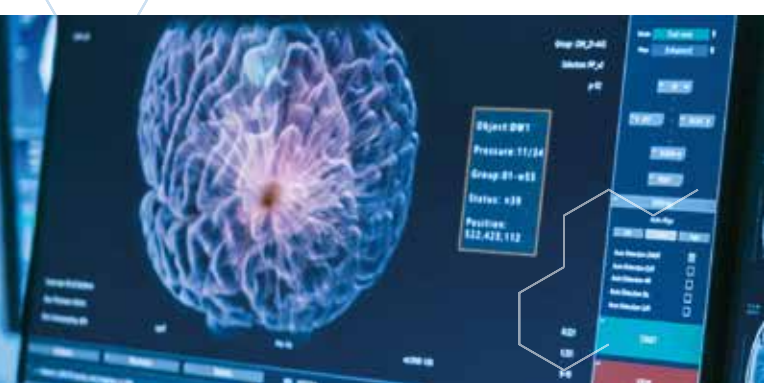
r3 - Resource procurement method agreed (must be agile)

It is standard practice for almost every business to have commercial frameworks with suppliers, adhere to tender processes and produce resource plans. While it is in the best interests of both client and supplier to have the right resources available, this is often not possible due to reasons such as timing, capability and cost. In a global market, where many of the same projects are done by similar organisations using the same pool of skilled people, market intelligence into the capacity of suppliers and internal procurement capability can make a significant difference.

Developing a strategic workforce and supplier procurement strategy and process will yield huge benefits when mobilising your team and starting dialogue with suppliers about their capacity and capability. It will also ensure a more realistic pipeline of delivery. If you codify this intelligence into your project-specific resource needs, your 'A-Team' will be available when you need it. Many of the major failures in projects can be directly traced back to a lack of resource capability.

Widespread recognition of organisational maturity has seen the rise and adoption of maturity models in all industries. CURED itself is a maturity model that, when applied, will significantly enhance the capability of your business. These organisational and operational enhancements will be felt by the whole project team, and rightly so – people are the most valuable resource.

People are the most valuable resource.



RESOURCE - Capability Meds

r1 Resourcing framework agreed

Once budgets have been developed and approved, the next step is to select the best way to procure the right people and tools for the project. Careful thought is needed to ensure that:

- **the method of procurement suits the specialist skills that are required**
- **the timescales for securing resources are aligned to the project's needs**
- **the estimation method and payment terms, which will vary when using a specific tender, direct award or framework, are considered.**

In certain instances, there may be geographical legislation that would constrain this process. This would also need careful consideration to avoid potential delays.

r2 Organisational capability assessment undertaken

CURED is about designing out some of the most prevalent issues that cause projects to fail. However, organisational capability is much larger than the topics covered here. Understanding where your weaknesses are is the first step to fixing them and there are several maturity models that can be used to ascertain your overall business capability.

These models have proven their value across many sectors and much empirical evidence exists to support their adoption. Upon assessment it will become clear which areas of the business need the most attention and also what the return on investment in change could be. This information is critical to securing the senior level buy-in and funding for business transformation.

r3 Organisational capability road map developed

Using a combination of CURED and industry-recognised maturity models will help you to build a picture of your future organisation and its needs. By combining these long-term goals with your operating model, you can create a road map of the technical, functional and cultural change that meets these needs.

To meet new challenges and take advantage of new opportunities in an achievable and agile way, this road map (and subsequent transformation plan) will need a phased and pragmatic approach that can be adapted as your organisation and its environment changes.

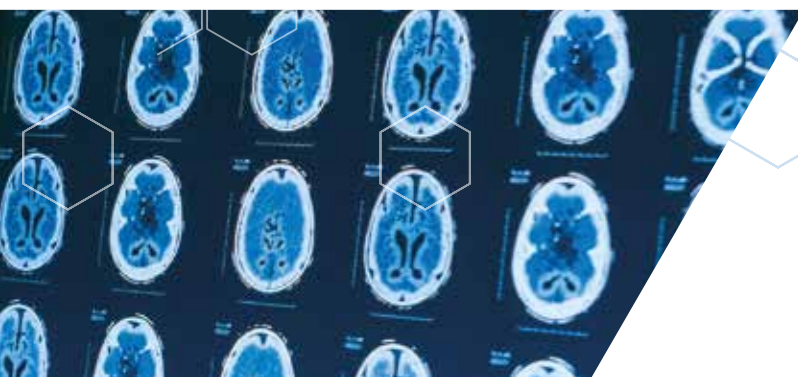
r4 Internal and external resources identified

There are obvious differences between securing resources from within your organisation or from the external market but what you ask for and what you need can vary a lot depending on your processes. It makes sense to look externally for specialist skills and internally for organisational knowledge, however, factors that are critical to success need the same core elements for both.

Understanding and codifying the capability that is specific to your project and its needs is fundamental to getting the right people on board. By predicting how your project will evolve over time, you can ensure availability of resource to allow it to adapt sustainably.

r5 Resource procurement method agreed

It is vital that internal and external procurement processes are aligned to your resourcing strategy before recruiting to support that strategy. Communicating and reviewing the output of the strategy is as important as identifying the criteria that informs it, especially if there are corporate or legislative constraints for recruitment and on-boarding.



r6

Resource budgets developed

A major fault in project management occurs when calculating the resources needed to deliver a project. Usually, there is little fidelity in the way that resources are calculated or a broad estimate is considered sufficient to start a project. Many of the highest-profile project failures can trace their woes back to inaccurate estimating. By implementing lessons learnt, having consistent data structures and applying best practice, you can derive and secure the budgets you will need to deliver the project.

r7

Competency framework agreed

Competency is a big issue for contemporary organisations. As the project delivery environment becomes increasingly challenging and the science becomes more complicated and innovative, maintaining best-in-class competency is increasingly difficult. You can no longer expect CVs and generic training to reassure you that your team is up to the task.

Recognising the evolving skills and competencies that your people will need during the life of the project is crucial. Having the correct blend of technical and soft skills will provide a rounded team that will work well together and with others.

r8

Improvement plan developed and agreed

Effective teams need robust processes to complement agile ways of working. In many cases, business processes may not align with how the business expects to work or with the needs of an ever-changing delivery landscape. To understand the most effective way of working and the processes needed to support it, you need to define your operating model. This will define how your team will need to work in each phase of the project.


Once these 'vertical slices' have been defined, they should inform a process suitability exercise that will highlight the areas that need attention. Once completed, the suitable existing or new ways of working should be codified into a live project execution plan. This will provide clear guidance on how you will lead your team in delivering the project and, in turn, this will increase stakeholder confidence.

r9


Project team engagement and feedback processes agreed and in place

When it comes to delivering complex projects, adaptability is critical to success. Building a competent and autonomous team that is flexible enough to overcome challenges and seize opportunities as they arise will significantly increase the speed and effectiveness of the project. To truly put the needs of the project first, each team member must have the right mindset and a thorough understanding of both the project's goals and the sponsor's strategic aims. Having a strategy and process for engaging the wider team and deploying tools to gather feedback on issues will demonstrate your commitment to put people first.





New ways to classify and influence people's behaviours have changed modern business. Senior management is routinely assessed and analysed for traits that complement strategic aims, and behavioural training is a proven fundamental part of project and commercial success.



Developing a strategic workforce and supplier procurement strategy and process will yield huge benefits when mobilising your team and starting dialogue with suppliers about their capacity and capability.

E is for Education.

The business environment is changing at an ever-increasing rate. The demands from regulatory authorities and new technologies mean that training and re-training are core parts of any successful business, whatever its size. Education is a life-long process about developing your personal capability and is different to training, where you need to be competent for a specific task.

The sheer breadth and depth of business functions and professions has led to a staggering amount of training providers and training undertaken. If you factor in postgraduate training and apprenticeships, the time and money spent by individuals and businesses on growing staff capability is huge.

A lack of specialist skills in project environments is a key strategic risk. As the world moves further into the digital domain, creating and maintaining an agile workforce that can adapt and respond to complex challenges can mean the difference between an organisation leading the market or being one that follows it.



A behaviour is something you do as a response to your environment. It can be positive, negative or neutral and is shaped by your values and motivations.

In a changing project environment, you cannot rely on a static set of core competencies. Knowledge must evolve with the surrounding world and how you use it is linked to business survival. The constant evolution of technology means that the tools we use in our day-to-day lives have changed beyond recognition since their origin. In solution-driven markets, recognising and harnessing 'the next big thing' can mean major gains for you and your business.

Developing competencies is much more than delivering training. It is about having the skills, knowledge and confidence to adapt what you know to meet specific challenges as they arise. Only by using education can you apply knowledge in a powerful way that can deliver innovation and maximise performance.

The key aspects of education to focus on are:

- **SKILLS – the tools and techniques you need to achieve and maintain optimal performance, no matter what is thrown at you**
- **KNOWLEDGE – what you need to do and why you need to do it**
- **CONFIDENCE – having pragmatic skills and knowledge that have been 'tried and tested' and that you trust to work.**

As you consider what you need to learn, you should also consider how you will learn it. In everyday life we are all bombarded with targeted information and have to decide what is useful or important and what is not. Traditional ways of education, involving classrooms and week-long courses, have been joined with a vast array of online and virtual training options. This has had huge benefits for virtual teams however thought must be given to energising a virtual audience and validating that new skills are landing positively and tangibly.

A recent trend is the growth in behavioural science and the research that has linked it to the workplace. The interest in IQ (intelligence quotient) has been enhanced with EQ (emotional quotient) – the ability to understand your and other people's emotions and how your behaviours affect each other. This behavioural insight has moved from the boardroom to the wider workforce, and with huge benefits.



Let's look at one of the education elements of CURED:

e5 - Team behavioural training complete

A behaviour is something you do as a response to your environment. It can be positive, negative or neutral and it is shaped by your values and motivations. If you are under stress trying to meet an important deadline in a project where bad news is not tolerated, a colleague asking you for help may trigger an unhelpful or unpleasant response. However, if the environment around you is supportive, your response is likely to be positive – and even more so if you also understand how situations can affect the way you behave.

By implementing e5, teams will understand more about each other. This will increase empathy, which will lead to better behavioural responses and better decision-making.

This principle must extend to all parts of the wider project to establish a shared set of positive behaviours, both measured and complied with. If you can identify wrong behaviours and promote the right ones, this reinforcement for desired behaviours will create a positive feedback loop in which morale will soar and your team will thrive. This, in turn, is likely to lead to a further benefit – a lower turnover of staff.

Another key development in education, and core to the principles of the CURED framework, is collaborative learning. Uniting people to overcome challenges as a team has been shown to greatly increase the impact of knowledge, and many training providers use group simulation to attain new levels of engagement. It is important to consider how your people learn as well as what they learn; not only at the start of a project but throughout its life.

We have already discussed the need for competencies to evolve to meet project challenges. The same is true for the approach to collaborative learning. Questions to be answered are:

- **Where are we failing to meet our potential?**
- **Who would benefit from this now?**
- **How do we know that our educational initiatives are effective?**

Building a collaborative and evolving learning platform will promote a shared base of competency and expectation, which will continue to inspire the team long after training has been delivered. Finding innovative ways to upskill your teams and evidence the successful application of knowledge is a core part of the CURED approach. Long-established apprenticeship routes to learning are built on the principles of applied knowledge and the demonstration of understanding through doing. With these principles in mind, it is possible to adapt other traditional approaches to learning.

An important last point is on the process of knowledge management, which is an area of concern for many businesses but, in our experience, does not get the attention it deserves. As your organisation grows, it can become dependent on the specialist skills of a few key individuals. This natural organic development means that although ways of working may fit your current, specific needs, you must first codify and optimise this tacit knowledge before you can then successfully build on it.

EDUCATION - Capability Meds

e1 Training programme developed

One of the core products of the educational journey is the training programme, which may be bespoke training for a project or generic training that spans the whole company – either way, it cannot be viewed as a one-off event. It should match the comprehensive competency needs of the team and be supported by truly engaging material and learning methods.

You must also ensure that you focus on soft skills as well as technical ones as these will make a huge difference in modern complex projects.

e2 Education needs analysis

Needs analysis is the core of an effective education programme. There are many inputs and approaches into this process that must be applied. Your own internal requirements should be mapped and framed in the context of the project; identifying emerging competencies will ensure your people are ready for change. It is also critical to consider your stakeholders' needs, as their ability to support or hinder your efforts using their knowledge and perspective should not be underestimated.

e3 Knowledge sharing and management capability in place

We have discussed the need to manage your internal knowledge and build a robust capability to truly provide a more agile way of managing your projects and business. Many project innovations occur because of an emerging need, so you should capture both the good and the bad – no matter what the source. Project teams are temporary management systems, typically comprising a coalition of different companies that have joined forces to deliver the project, so you need to ensure that those 'lightbulb moments' do not become temporary themselves. By recognising the importance of this function and building processes and tools to capture knowledge and lessons learnt, you will be investing in a better future.

e4 Staff and stakeholders are educated

Once you have understood the educational needs, it is time to deliver them. This may sound simple, but it can be a huge logistical challenge. Consider the ongoing operational impact of training – because taking time to learn on a large scale will clearly affect your business performance. Innovation in learning tools and techniques can lessen the impact, without decreasing the effectiveness of training. Cross-organisational endeavours must be used where knowledge is relevant for the wider team. It is essential to achieve a shared and common capability, so supplier collaboration in this area should be at the top of your thought processes.

e5 Team behavioural training complete

We cannot understate the importance of the impact of positive behaviours on performance, and this fact features heavily in the CURED framework. Having a self-aware team that wants to succeed and is willing to change to do this will greatly increase your chance of success. There are many different methods and models available to help you achieve this insight, so thought must be given to selecting the most appropriate method for you and the wider team. The guiding principles of team behavioural training for those involved in project delivery are to foster honesty, trust and a willingness for self-improvement.

As you consider what you need to learn, you should also consider how you will learn it. capability.

] is for Delegation.

Delegation can be a surprisingly emotive subject. Simple in concept but less so in practice, it can seem to senior management that there is a lack of control around what people do in projects. Cumbersome business processes and governance take valuable time away from managing the project and can contribute to delays. Too much autonomy is often equated to a deficiency in the traceability of decision-making. When combined with a lack of trust concerning the ability and commitment of suppliers to deliver what is required, this leads to unnecessary oversight and, conversely, project teams can feel micro-managed. It is important to note that both perspectives are typically simultaneously present and interrelated.

Delegation is at the heart of good governance, which can make all the difference to projects and businesses. Delegation applies not only to corporate governance but also to projects. Understanding the scope of each project and its associated roles and responsibilities defines the scope of decision-making. Introducing flexibility yet maintaining a handle on robust control is a challenge that cannot be ignored.

One of the key outcomes of effective delegation is delivering the ability to streamline change control and approvals. A good plan is merely a best guess – it doesn't become fact until it has been implemented. Your business and/or project will have to deal with change on a constant basis. The rate of change you need to manage dramatically increases with project complexity. The application of c3 - Project complexity assessed in the CURED framework will ensure that you understand the expected rate of change and where it will come from.





Regardless of the scale of the challenges, giving your people the right tools and processes to streamline how they adapt is critical. By taking a lean and end-to-end approach to project governance, you will have a full picture of functional interfaces, change approval and how each part of your project and business interacts with the other to deliver its goals. Optimal governance is a fine balance between steering progress and creating bottlenecks that drive a tendency to micro-manage, which ultimately undermines the effectiveness of delegation.

A key design input in achieving agile governance is an understanding of accountabilities and responsibilities. Although this may seem obvious, a lack of clarity in this area is common and causes a multitude of issues. Roles and responsibilities are not simply part of a job description; they are the building blocks of an efficient and capable team and organisational culture. Being clear about your own scope of control and when and why you need others will significantly increase your effectiveness, speed up the decision-making process and avoid duplication. It will also reinforce accountability, which is a critical factor in driving desirable behaviours and therefore project success.

Another factor to consider is that the decisions people need to make will change over the life of the project. Keeping the design principle of 'agility' in mind as a core process is very important.

Delegation is fundamentally about letting go; it is giving someone else a task and trusting them to do what you are ultimately accountable for. It is here that good leadership can really deliver value, but this is reliant on the 'team' accepting the responsibility that has been given to them.

Let's look at:

d1 - Leadership programme developed

Effective leadership is one of the most important competencies of any project or organisation. It occurs at every level of the project, gives the project team vital context and understanding, and inspires everyone to work in the best interests of the project and its goals. The right behaviours are key to an effective and autonomous organisation. If leadership training is part of everyone's personal development, it will eventually become part of the DNA of the organisation. As mimicry is a basic human trait, the number of role models will grow organically throughout the project and organisation.

Developing a leadership programme that aligns with the messages and goals of the project is fundamental. Although some organisations will have a well-developed leadership programme, adapting their general business values and goals to match the specifics of a project can be highly challenging. You should ensure that your leadership programme is relevant to the goals of the project and that it works for your team.

Once your operating and behavioural leadership model has been developed and codified, this information needs to be socialised to the team and related stakeholders. This may sound simple in theory but communicating effectively can be a major challenge. The way that people engage with information changes constantly so there is a need to consider the most appropriate approach to ensuring messages are understood and stakeholders are kept engaged.

Leadership, delegation and trust are all intrinsically linked and issues around trust are a big challenge for all organisations. Projects are often not set up to take an evidence-based approach to decision-making, which fuels mistrust and compromises their ability to make progress. Senior managers may revert to short term 'fire-fighting' interventions that can hinder overall progress instead of focusing on the bigger picture and making sound strategic decisions. This is frequently caused by a lack of reliable data and situational information alongside the absence of the right competencies, leading to fear and mistrust. Setting the right level and quality of information to help make informed choices at each level is absolutely critical in making the best decisions. Building trust through transparency should be your goal and it is important to focus on insight and intelligence – not just data.

Finally, it is good practice to reinforce decisions around delegation through assurance. Assurance is a core control function and often a regulatory requirement. It enables objective oversight and allows for continuous improvement if applied well. It is also a good way to reinforce accountability and build confidence, both internally and externally whilst having the capability to showcase your project. Coupling a sound assurance strategy with a plan that is focused on the key risk areas is crucial. Assurance should be objectively delivered by resources inside and outside the project and continuously reviewed for suitability, as this is another function that must evolve with the project.



DELEGATION - Capability Meds

d1

Leadership programme developed

As we have discussed, leadership is a critical success factor for any project. There has been a huge increase in awareness, analysis and transformation in this area and most boards of directors are familiar with the concept and its importance. Accepting that the flow of leadership is multi directional across the project environment is the next level of maturity for projects and forward-thinking businesses, although it is rarely applied. Developing specific core competencies around leadership that are embedded and demonstrated by senior management and leadership will deliver an effective, empowered project team.

d2

Project governance defined and aligned to corporate governance

Governance is often thought to stifle innovation and hinder projects, but it can hold huge benefits when developed and applied correctly. We know that as complexity increases so do the challenges. Our brains can struggle to cope with multi-disciplinary, multi-faceted and technically complicated projects. Having a set of clear checkpoints that help us to ask ourselves the right questions is a powerful tool to overcome these challenges. Effective governance facilitates this.

Project governance should be aligned to corporate governance to streamline approval processes and to also give a vital understanding of how the overall organisation supports the project. There needs to be a golden thread running from corporate strategy and mission through to corporate and project governance. Misalignment of these will create greater complexity and mistrust, contributing to poor leadership and an unwillingness to delegate.

d3

Levels of delegation set against risk and trust thresholds

Delegated authority defines the levels of which change and spend for example can be approved. They typically increase in line with the seniority of roles within an organisation. Businesses will often have a series of financial or risk thresholds and a change approval and authorisation process.

The application of delegated authority levels cannot be standardised but should be defined to align to the risk and complexity of each project i.e. a project with greater risk exposure requires increased levels of delegation and conversely low a project with low complexity should have greater autonomy.

d4

Area of expertise and control understood

Establishing the right delegations, governance, and assurance on their own is not enough to drive good project delivery. Understanding the strengths and weaknesses of your competencies will highlight gaps and determine essential expertise required to deliver effectively.

After understanding your project's requirements during the organisational design phase, you should validate the core competencies of the people involved. As this may increase the investment needed to upskill through training and accreditation, you should include a provision for this in your training programme.

d5**Roles and responsibilities clarified and agreed**

- It is important that all roles and responsibilities reflect your project's needs and are part of the training that people receive. Typically, there is a disconnect between the values and aspirations of an individual and their organisation.

The absence of clear and agreed roles and responsibilities results in people adapting to their role and their personal objectives rather than that of the team or the project. This is a problem when organisational design for the project and the associated roles and responsibilities are not agreed and appropriately applied. This can lead to duplication of effort and a lack of clarity around the decision-making process that will, in turn, lead to project delays and escalating costs and will perpetuate adverse team dynamics.

d6**Decision-making processes optimised**

- When developing project governance and delegations, there is an opportunity to review how decisions are made and how they could be streamlined to maximise efficiency. Process flows can be complex, so care and attention are needed to ensure that all parts of the decision-making process are accounted for in your design. These should be based on organisational governance whilst aiming to increase efficiency where possible. The application of management methodologies such as Lean and Six Sigma may help to achieve this.



d7**Level of autonomy set against organisational rules**

- Levels of delegation should align with the rules set by the sponsor organisation and any regulatory bodies. As previously mentioned, organisational rules must be suitable and relevant for the time and environment in which the project is being delivered. Whilst alignment is fundamental, you and your team must feel empowered to challenge and improve these processes when opportunities arise.

d8**Assurance strategy defined and implemented**

- The assurance process can be a powerful ally to projects and project teams. It should consider key points and risks during the lifecycle of the project and provide constructive challenge to help projects to be in the best shape to move forward. These key points are time dependant so a pragmatic and properly resourced assurance plan should be developed.

The assurance plan should be integrated with the project and be well communicated to the team and stakeholders. Assurance methods will incorporate business processes, internal peer reviews and external assurance reviews. It is important to ensure objectivity and promote collaboration to unlock the value of your assurance activities. When applied effectively, assurance can significantly increase stakeholder confidence and your chances of successful project delivery.



CURED is a collaboration of individuals, organisations and sectors and we would like to thank everyone who has been directly involved and those who have inspired us to make this journey.

Another key thing to note is that CURED is a live capability model that will adapt over time as it is applied. As it evolves, we will update the code and the website with the latest and most impactful knowledge to help your projects thrive.

We hope that you have found some insight and practical tips to get teams working better together which, ultimately, is best for everyone.

The CURED framework team.



References



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Company profiles of the CURED founders

The authors of this Code of Practice have a history of collaboration in the pursuit of knowledge. Having worked together for over a decade, the development of the CURED framework and associated tools, detailed in this Code of Practice, represents the culmination of their shared goals for legacy and positive impact. Working together with the Institute of Clinical Research in an ever-evolving landscape, they are raising the bar for collaboration and excellence in the delivery of clinical research projects.



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David Bryde is Professor of Project Management and Director of Research and Knowledge Transfer at Liverpool Business School, Liverpool John Moores University. With over 35 years of experience in project management, firstly as a practitioner and latterly as an academic. He is widely published internationally, with in excess of 100 academic journal papers, research monographs, book chapters, conference presentations, invited keynote speeches/guest lectures/presentations, expert interviews and articles. He is currently the Lead Project Coordinator for a four-year large scale EU-funded research programme titled "Being Lean and Seen: meeting the challenges of delivering projects successfully in the 21st century".

th3rdcurve

Th3rdCurve was founded on the principles that controls can and should be helping projects, programmes and portfolios achieve successful outcomes. Many organisations have yet to tap into the power of controls and reap the benefits that having robust controls in place inevitably brings. Our unique insight has been developed from many years of major programmes experience, and it is our knowledge of the application of best practice principles that can enable any organisation to realise its delivery potential and beyond.



1to1to1 is the project management consultancy business arm of R. & N.R. Consulting Ltd. It specialises in project management consulting and training focused on drug development, with over 30 years' experience in clinical research from both the CRO and Pharma perspective. It is actively involved in academic research and has a long-standing relationship with Liverpool JM University, where our principal consultant, Roger Joby, is a visiting research fellow. 1to1to1's aim is to help organisations improve project performance by applying relevant academic research and practical experience.

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