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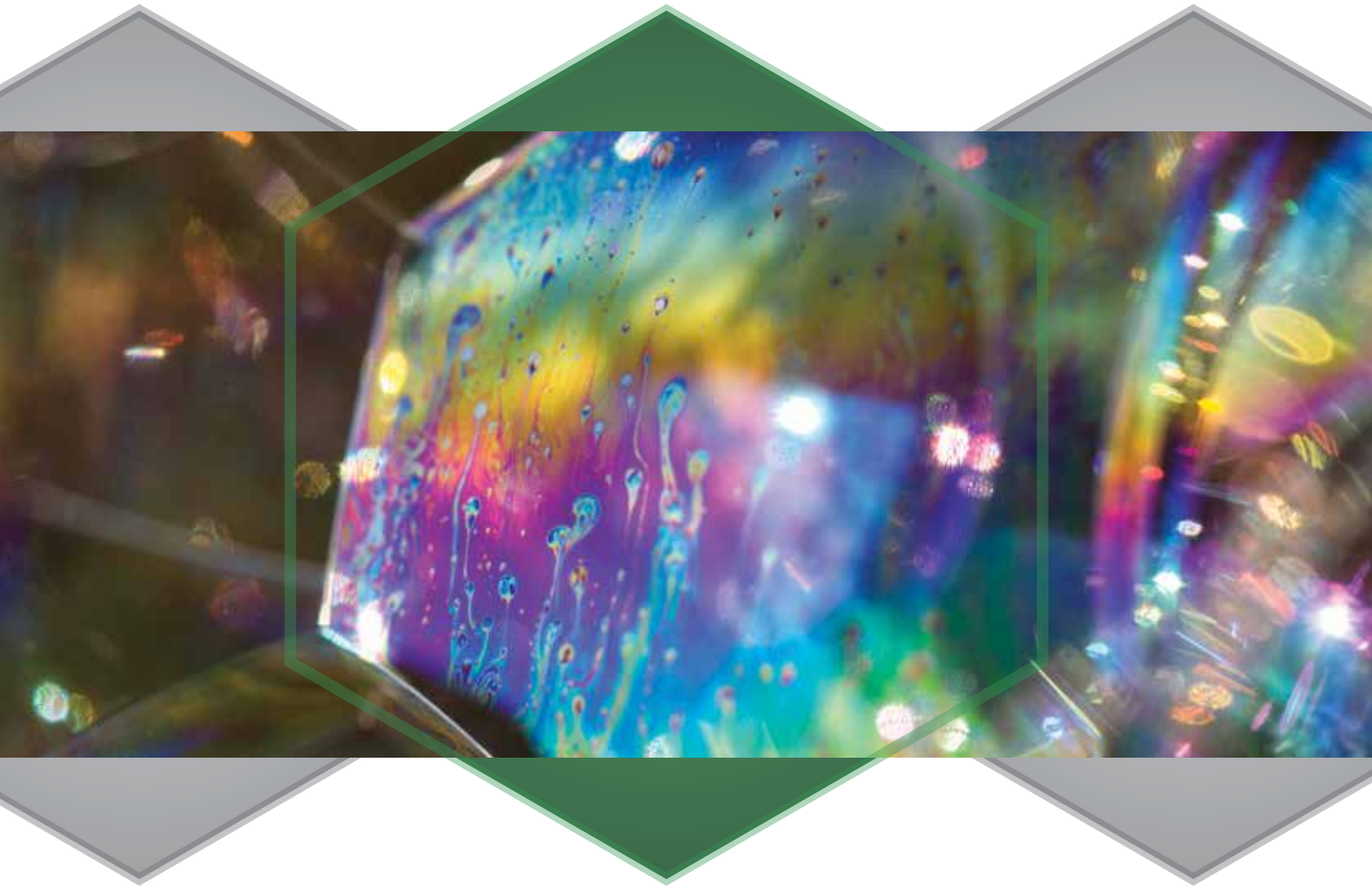
Clinical Trial Management Information:

A Guide to Implementation



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Summary

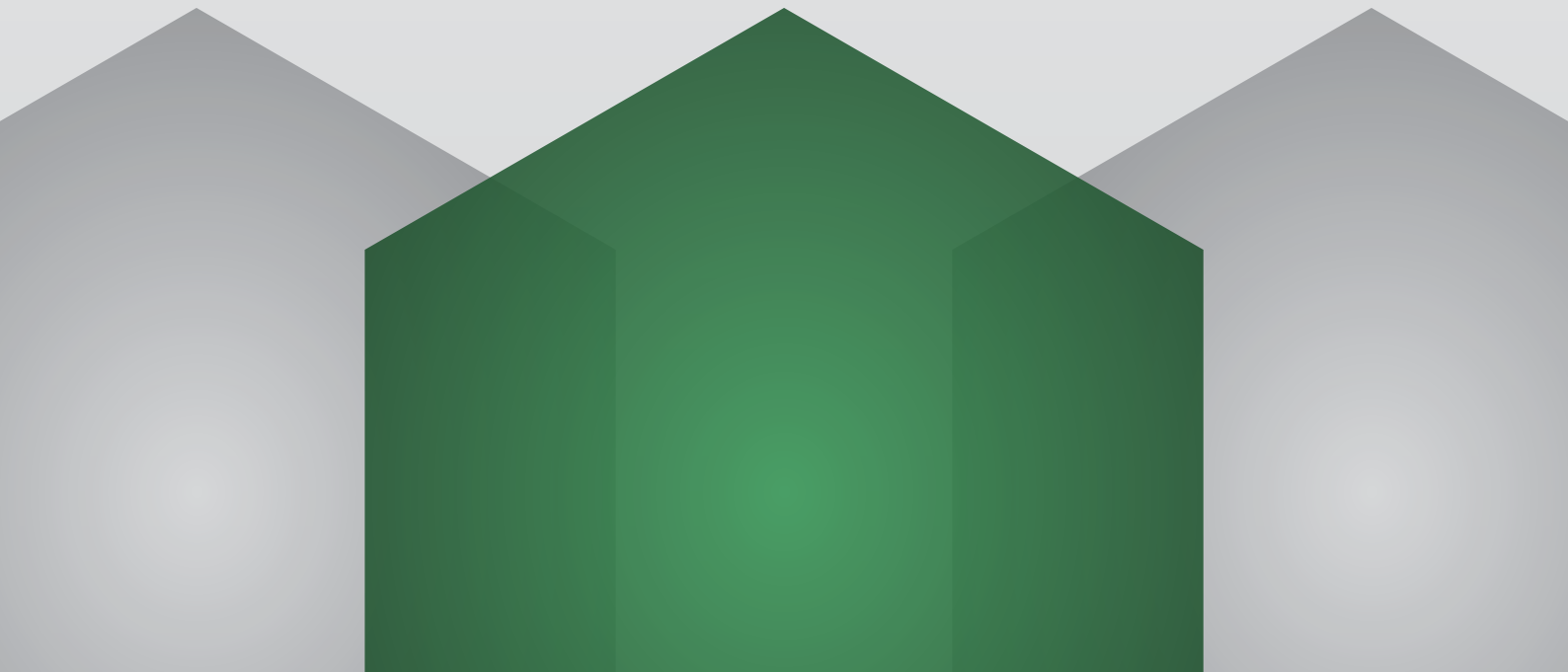
Possessing a clear and accurate picture of clinical trial management information provides key strategic advantages and safeguards against serious compliance risks. However, among the myriad priorities in pharma business improvement, it can often be overlooked.

Over the last decade, internal and external changes in the clinical trial environment have driven a radical evolution in the information systems landscape, often resulting in ad hoc solutions that aren't fit for purpose, and lack a 'single source of truth'. Users across functions find themselves without the information they need, when they need it.

New and innovative approaches have emerged in the industry to manage clinical trial information, from centralised data systems to mobile device integration. But as companies' needs continue to diversify, it is becoming harder to find a 'one size fits all' solution.

Kinapse believes that evolving the clinical management landscape is more than a matter of simply upgrading systems. Shifting trends and advancements in the industry necessitate further considerations, including organisational strategy and the increased demand for information reuse, internally and externally.

To successfully evolve the landscape, a critical, systematic and holistic approach to change is needed; an approach which incorporates an in-depth assessment of existing systems, future needs, potential solutions and change management, and above all, places the user at the centre.



Clinical trial management information is a strategic asset

Clinical trial management information is used across a pharma organisation from the study team to the corporate level. Each user group requires this information at varying levels of detail to make key decisions.

1. Study managers:

Require management information to ensure that studies are delivered on time, to budget and to required quality.

2. Program managers:

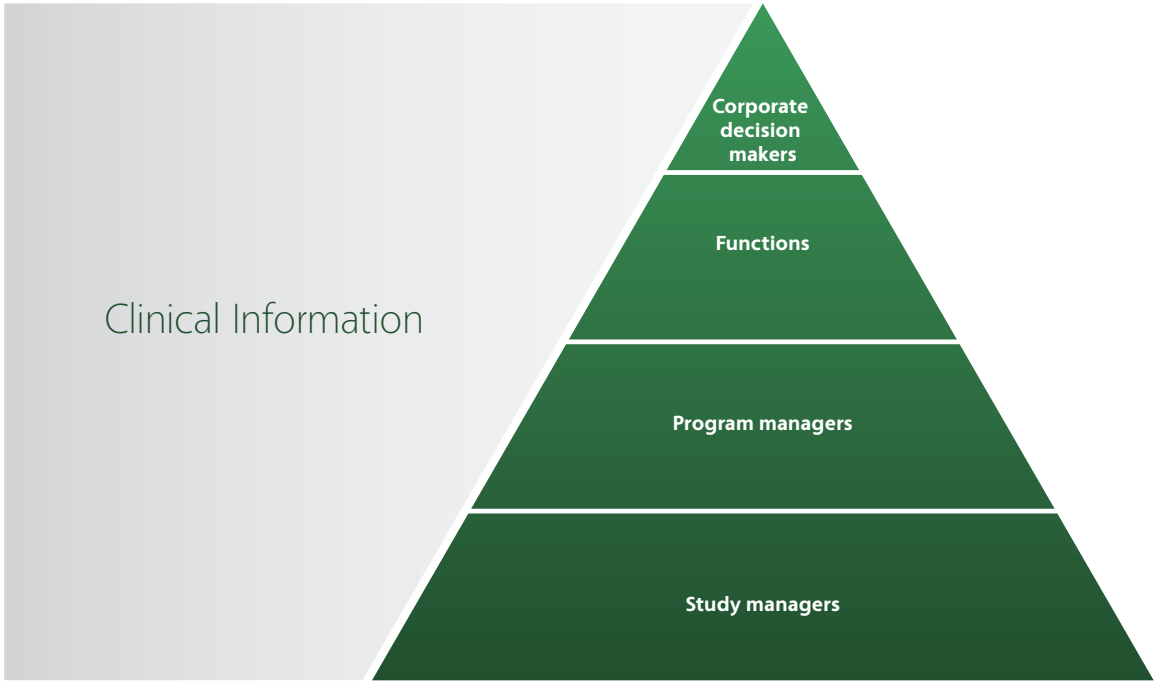
Use information consolidated across a group of studies to manage budgets and risks.

3. Functions:

Need information on studies' progress, e.g. Regulatory Operations, Clinical Trial Disclosure and Pharmacovigilance functions that need information on study milestones and patient exposure in order to support regulatory obligations and submissions.

4. Corporate decision-makers:

Having a complete, current and prospective understanding of clinical studies allows executive members of the organisation to make strategic decisions, for example, on portfolio progress and outsourcing strategy.



Changes in the clinical trial environment are driving a radical evolution in the information landscape

Over the past 20 years, the Clinical Trial Management System (CTMS) has emerged as the centrepiece of the clinical trial information landscape, enabling planning, tracking, and reporting functionalities. In the last decade, a number of changes in the clinical trial environment have presented challenges to established CTMS systems, driving rapid, but often disjointed, system adaptations. These changes fall into the following four categories.

1. Greater number, complexity, and cost of clinical trials.

With companies undertaking larger clinical trials, more globally, systems have had to grow to accommodate a greater volume of increasingly diverse data. The increase in costs of studies, within a more cost-conscious environment, necessitates greater transparency in expenditure and return on investment.

2. A greater diversity of stakeholders internally and externally.

More stakeholders within a pharma company need clinical trial management information to support newly emerging areas such as clinical trial disclosure and risk-based monitoring (RBM). In addition, external partners including regulatory agencies and co-development collaborators require an expanding range of trial information.

3. Increased outsourcing of clinical trials.

Information derived from CROs has become an important component of the information landscape following widespread, large-scale outsourcing of clinical trials. This creates challenges in establishing an effective exchange of information between the sponsor and vendor(s).

4. Regulatory changes.

Regulatory bodies now require more information from clinical trials. In response to increased regulatory scrutiny, vendors have attempted to incorporate these requirements into CTMS, e.g. FDA e-signature.

With these changes, the range of demands placed upon CTMS has grown well beyond its original remit - to manage a clinical study. The resulting systems have often become an unwieldy amalgamation of tools and databases, with a multitude of internal and external interfaces, ultimately unable to handle the strain of the demands coming from all directions.

Widespread issues with the existing environment signal the need for a redefinition of the landscape

Many companies, having been forced to adapt to changing demands, are confronted with a number of emerging issues and challenges. Existing architectures are not delivering the information required to support operational and compliance requirements, and consequently those responsible for these systems experience significant pressure to deliver to expectations.

In Kinapse's experience, working directly with top-10 pharma companies, three main issues have been encountered.

1. Unreliable and inaccurate data.

The overwhelming complaint voiced by users of a system landscape which has evolved organically is that there is no 'single source of truth.' As data is often stored in multiple locations, updates in one system are often not reflected in others, or at best reflected after a significant time delay. This leads to contradictions in key data, non-standardised definitions, and inaccurate reporting. To achieve full compliance, data must be trusted and reliable, with, for example, sufficient reporting on patient exposure. The consequences of not having this information available, or in contradiction, may not only be a serious compliance risk, but also a threat to a company's licence to operate.

2. Inefficient processes and governance.

Where a fragmentary approach has been taken to system upgrades, supporting processes have been designed in isolation without taking into account the wider information landscape structure. This has resulted in time being spent on manual data entry or manipulations, often leading to poor overall quality.

3. Complex and poorly-integrated systems.

The multitude of systems with complex, independent interfaces leads to information being isolated, and users being unclear about the existence of data or reports. Excessively customised tools have left users confused about where and how to access the information they need.

System technology trends in the industry

The growing need for a redefinition of the landscape has triggered a number of systems and design responses in the industry. Of these, four major trends have emerged:

1. The creation of an Operational Data Warehouse

The growth in the amount of clinical trial management data, and their range in diversity of source and scope, has led many companies to develop a 'hub and spoke' IT architecture model constructed around a central data repository, often called an Operational Data Warehouse (ODW). All information is then sent directly to the central database, which becomes the 'single source of truth', enabling all functions and departments who require the data to be sure that it is current and accurate. Key components of this model are noted below.

- A separate reporting environment:

  The ODW acts as a large database housing all management data across all trials. When data are needed, they are extracted according to the fields and ranges required for specific purposes. Reporting occurs in a separate environment connected to the ODW, often through data-marts which filter data needed by specific company functions. It is within this standalone environment where more complex and innovative approaches such as RBM can be implemented.

- Clearer and better-defined CRO data flows:

  With this model, CROs' data is sent directly from their CTMS (or other systems) to the ODW, and then used for further reporting and analysis as needed. An important aspect of this arrangement is the definition of a set of universal data requirements and master data definitions; CRO data which may come into the ODW from a variety of different systems must be defined consistently to maintain a coherent dataset within the ODW and avoid misinterpretation. The model also allows for the sponsor's reference data (e.g. investigator details and unique trial identifiers) to be sent to CROs.

- Taking the weight off the CTMS:

  The role of a CTMS in this context is ideally as a transactional system managing input trigger events and helping teams run studies. All data will ultimately be pulled from the CTMS into the ODW for analysis and reporting. With an ODW, CTMS can become more transactional in nature and be extricated from the centrepiece of the IT structure, allowing for a far more flexible plug-and-play architecture that can evolve with changing needs.

2. Questioning the role of CTMS

The widespread issues with legacy CTMS systems, and the adoption of ODWs with corresponding reporting environments, question the role of a CTMS in the wider system architecture.

Kinapse has found that, despite the allure of a complete CTMS removal, CTMS involvement in a systems landscape is largely dependent on operating model and outsourcing strategy:

- Large-scale in-house studies:

Pharmaceutical companies running large numbers of studies in-house, or CROs conducting studies for trial sponsors, will still need a CTMS to support study execution.

- Full outsourcing strategy:

When no in-house trials are conducted, some organisations have considered the complete removal of a CTMS. While the removal of the CTMS structure presents no intrinsic problem, some data which have historically been held in the CTMS are not incorporated in other systems, such as trial master data including: site information; investigator details; study team details; countries and site past performance. Not keeping track of this information can present problems in CRO interfacing.

- Mixed outsourcing model:

Companies employing a blended operating model - running some studies themselves and outsourcing others can find a flexible solution by engaging with smaller, more versatile vendors who offer *ad hoc* CTMS services. Depending on the extent of in-house studies, companies can either build in a CTMS module which remains dormant until needed, or leave any permanent CTMS capability out of their system structure and instead utilise an external CTMS service when needed.

3. Increased flexibility for users

Technological innovations have allowed for greater flexibility for study teams and monitors in inputting, accessing and analysing data. These innovations can bring long term savings in efficiency, and also provide users with a more intuitive way of working. Examples include:

- The use of apps for remote interaction with study data
- The replacement of laptops with iPads or other tablets
- Solutions that take advantage of current embedded Microsoft Office solutions such as SharePoint and Excel, allowing companies to implement systems without large-scale reinstallations of new hardware and software.

4. The emergence of cloud-based SaaS solutions

Some system vendors are offering cloud-based services to replace entire on-site clinical information systems, including Electronic Data Capture, CTMS, reporting, and analytics tools. These services often function as a complete online platform consisting of a suite of separate modules with trial-related features, so that companies can pick and choose the modules that they need.

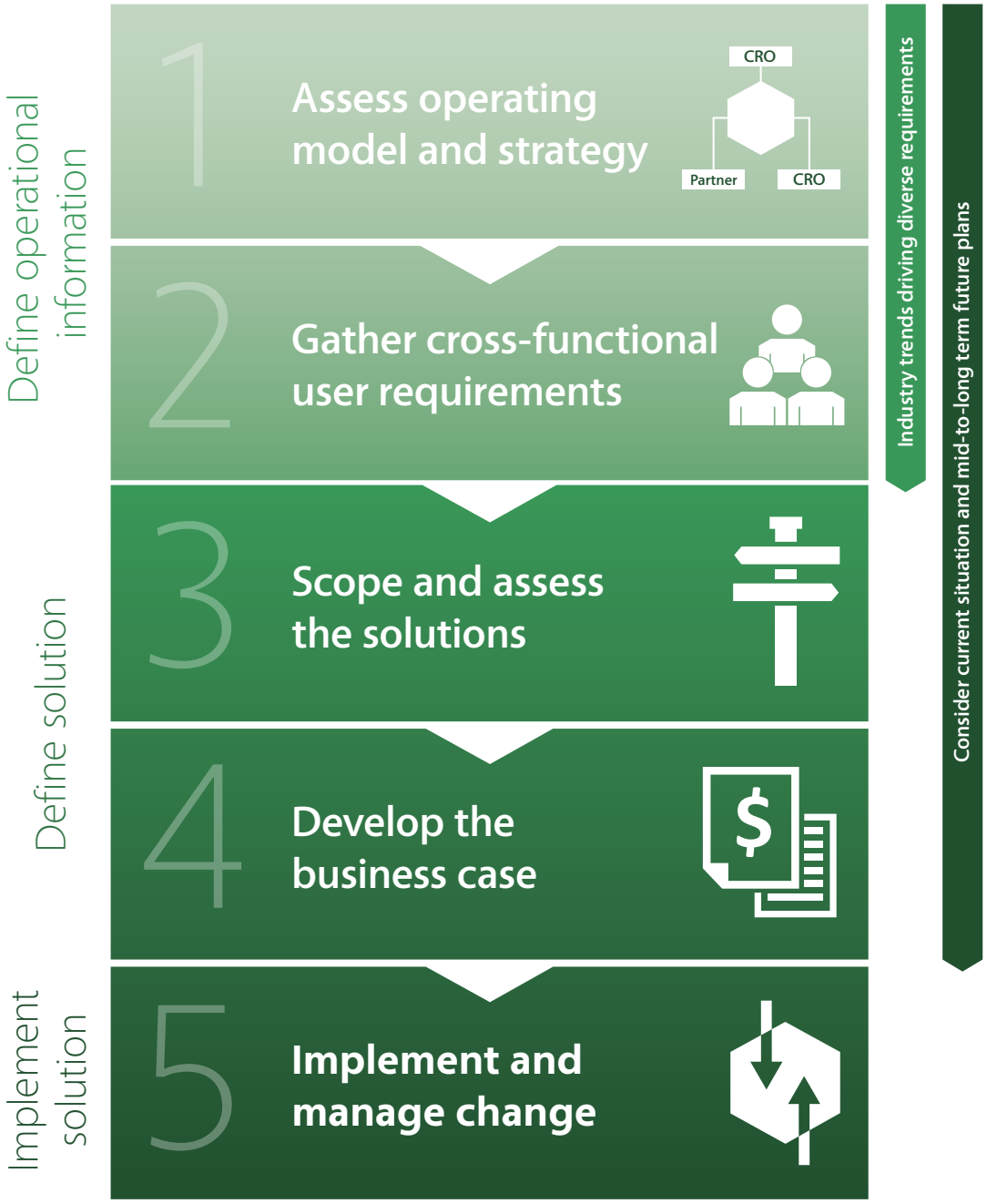
Fully integrated online systems like those offered by SaaS (software as a service) providers can solve many of the problems a small to medium-sized company may have with limited IT resources to set up and manage a complex system.

However, on-site server-based solutions still offer certain advantages. On-premise solutions allow internal control of data, which can provide benefits to some organisations, including simplicity in data retrieval, and less complex transfer of data between organisations. With rising concerns across industries over data privacy and confidentiality, on-site solutions remain attractive to many large pharma companies' leaders, as they allow internal control of security, privacy and disaster recovery policies and procedures.

Kinapse's methodology for a successful evolution of the clinical management information landscape

Technological innovation in the industry has allowed for choice and created the potential for pharma companies to develop advanced and streamlined system solutions. Kinapse believes, however, that to capitalise on this industry progression it is first necessary to understand your own company's strategic vision and requirements, and to plan and manage the changes with foresight. To do this Kinapse recommends a methodical and critical framework.

A solution developed using this framework will provide confidence that end-users will receive the information they need, when they need it.



1 Assess the operating model and future strategy

The depth and breadth of outsourcing and the impact of future changes on the operating model and strategy must be considered at the outset of the design of the clinical management information solution.

Outsourcing strategy

An organisation's partnership structure and the extent of trial outsourcing will dictate aspects of internal systems set-up, as different types of outsourcing require individual approaches for optimum systems structure. For companies engaging in large-scale, full study outsourcing, a central data repository can act as the focal point for multiple external partners.

However, Kinapse has found that completely removing CTMS functionality from the internal system landscape will reduce the organisation's ability to oversee the performance of their internal trials.

Industry trends will drive wider requirements

With the industry environment constantly evolving, a clinical management information landscape being built today must be sufficiently flexible to adapt to potential future changes, such as:

- changes to ways of working, e.g. greater use of real world evidence;
- new regulations and emerging trends, e.g. RBM and clinical trial disclosure;
- potential collaborations with other life sciences organisations or industry initiatives, e.g. the Transcelerate investigator portal.

2 Gather cross functional user requirementss

A system design drawn from users' needs will create an environment specifically tailored to the tasks and functions required to support processes, rather than an environment in which the system dictates the processes.

In addition to study management, the information system must ensure that the right people in other functions, such as corporate finance, portfolio management and vendor management, can access the trial management information they need.

Therefore, it is necessary to ascertain:

- what operational data, reports and analytics are needed, and by whom;
- what level of detail will be required by different functions;
- how often data will be accessed;
- the mode of delivery.

This information is then used to construct a clear information map laying out the information flow throughout the organisation and how best to create a user-friendly reporting and analytics environment.

3 Scope and assess the solutions

When a clear picture of the current and future organisational strategy, user requirements and existing gaps has been identified, the next stage is to develop options for viable solutions.

Constructing a set of suitable options requires matching the gaps and user requirements with either small fixes or long-term integrated changes to the following four areas.

- Systems: Updating out-of-date systems, those no longer performing the functions they are required for, or which are too difficult and expensive to maintain.
- Governance and Accessibility: Establishing changes so systems can generate the required reports/management information with the appropriate level of granularity, minimal manual intervention and adequate control. Examining the timeliness of receipt of required data, and whether those who need the data have access.
- Processes: Ensuring a network of processes that are developed entirely with user needs in mind, creating effectiveness and efficiency without redundancy.
- Culture: Ineffective existing systems often negatively affect employees' perception of the overall landscape and, as a result, performance. Improving this perception to ensure meticulous data entry, accuracy and effective maintenance of databases will increase data quality.

Selecting the optimum solution requires a number of considerations.

- Capability Realisation: The most important consideration is the extent to which the solution bridges the gaps identified. Capabilities should be ordered by priority.
- Timelines: Implementation should be phased, allowing for a synchronised approach ensuring stakeholders are ready to take on board changes. Avoiding a 'Big Bang' implementation, which can cause great disruption, is essential to ensure a smooth and stepwise transition.
- Risk/Ease of Implementation: Factors such as platform compatibility and business continuity will impact implementation planning. For example:
  - retiring current systems;
  - the presence of in-house technical expertise;
  - how many people will need training in the new system;
  - resource availability.
- Cost: Cost will often be dependent on the complexity of the company's current setup. It may be the case with highly complex existing structures that system replacement would entail such vast restructuring and migration that it is ultimately not worth the cost. License requirements must also be taken into account at this stage.

Sample solution assessment:

	CAPABILITY REALISATION	APPROXIMATE TIMELINES (MONTHS)	RISK/EASE OF IMPLEMENTATION	DEPLOYMENT COST AND COST OF OWNERSHIP
OPTION 1* New environment with an Operational Data Warehouse and 'one-stop-shop' for reporting	Delivers required capabilities including support for operating model	18-24	Manageable risk - solution used by other companies	**Deployment cost:** Medium to high **Cost of ownership:** Medium
OPTION 2* Upgrade legacy system with minor enhancements to the existing reporting environment	Does not meet requirements around operating model and fails to address fragmented reporting delivery	12	Low risk - No large scale architectural changes enabling business continuity with current software	**Deployment cost:** Low-medium cost **Cost of ownership:** Medium and increases over time
OPTION 3* Fix the existing architecture – no major application upgrades	Does not meet requirements - current legacy system lifespan limited	<12	Medium risk - no technical changes, but maintenance requirements will continue to increase in tactical landscape	**Deployment cost:** Lowest **Cost of ownership:** Increases over time

* It was also recognised that improvements to governance and processes were necessary for all options to address serious concerns in data quality

4 Develop a business case

Having assessed potential solutions, it is essential to create a clear business case for a more accurate view of the impact each option would have on the company. If more than one option is considered suitable, creating a framework business case for each can help narrow the options; this also applies where there are multiple variations of one solution.

Included in this will be:

- understanding the main components of the solution;
- calculating detailed costs;
- scoping implementation timelines;
- performing a risk analysis, and qualitative and quantitative benefit assessments.

5 Implement and manage change

Once a solution has been chosen, the implementation process begins, with robust planning, mitigation of the impact on ongoing trials, and allocating the right people to manage the change.

Conclusion

Clinical trial management information is a critical asset, however, internal and external pressures have made systems evolve in an unstructured, piecemeal fashion, creating landscapes that are not fit for purpose.

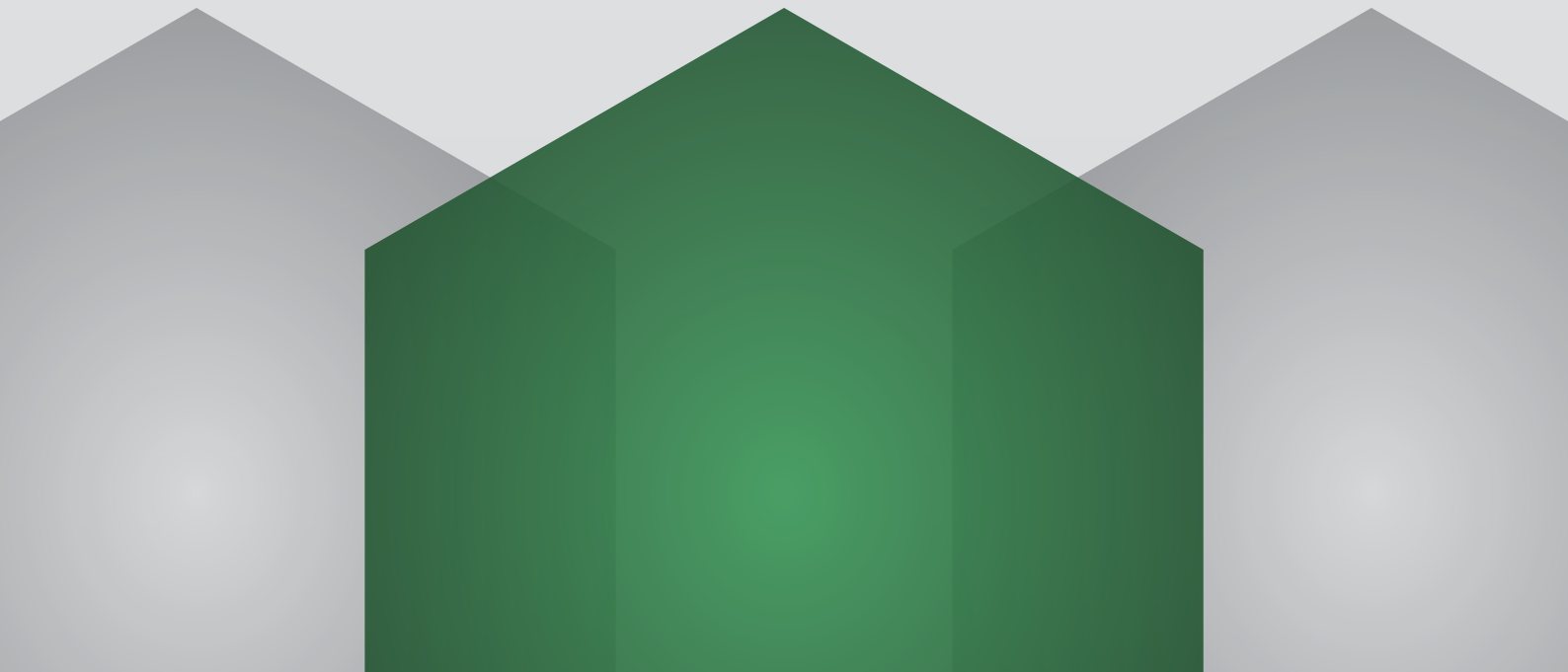
Kinapse recommends that to build a robust clinical trial management information solution, a methodical and critical approach must be taken. Companies should examine their mid- to long term organisational strategies and user requirements whilst considering industry and regulatory advancements. This will create a fit-for-purpose solution designed to provide the organisation with the information it needs, and the ability to access it.

About Kinapse

Kinapse provides expert advisory, capability building and operational services to the life sciences industries. Our mission statement is: 'Collaborating with our clients to innovate for exceptional results'. Kinapse clients include many of the world's leading pharmaceutical, biotechnology, medical device and specialty pharmaceutical companies, government organisations and life sciences service providers.

Our key advantages are:

- Focus on the life sciences industries
- Deep industry experience and technical acumen
- History of successful project delivery



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