





### Challenge

- Develop performance metrics related to the effectiveness of 20,000 global clinical research associates (CRAs)
- Optimise clinical trial processes and consolidate vast volumes of data from multiple disparate sources, including clinical trial management platforms and site management systems



### Solution

- Human-centred design thinking workshops
- Scalable analytics solution with intelligent KPIs, powered by artificial intelligence (AI) and equipped with embedded governance
- Comprehensive business intelligence and operations performance reports dedicated to unifying action and accelerating results



### Results

- By streamlining and accelerating the startup time, and automating the effectiveness of global CRAs, clinical trial processes have been optimised
- Faster innovation is facilitated by quickly uncovering insights, patterns, predictions and recommendations at scale
- Data consolidation with better visibility ensures processes are transparent, auditable and compliant with regulatory requirements



# Transforming clinical trials with intelligent KPIs

This multinational pharmaceutical organisation is committed to developing innovative drugs to meet the unmet needs of patients and make the impossible possible. The company has introduced over 70 innovative products to China over the past 30+ years, including original drugs and vaccines.

The goal of the Centre was to obtain a scalable solution to track the performance of each CRA, especially on large, global Phase 3 studies where complexity of regulatory requirements vary, as do logistical challenges associated with ethics review, drug supply and biospecimen management.

Critical to its success, the pharmaceutical organisation's Asia Pacific research and development centre (the Centre) based in China, provides comprehensive support services – including clinical trial management – for development projects across the company's global product line.

### Scaling clinical trials for success

Clinical trial activation and management is one of the research and development hub's most manual and time-consuming processes.

The Asia Pacific Centre runs around 100 worldwide clinical trials concurrently, ranging from small Phase 1 to huge Phase 3 studies. The Centre's clinical research associates (CRAs) are crucial in conducting clinical trials by ensuring integrity, quality, and compliance with study protocols, standard operating procedures (SOPs), and regulatory requirements.

Specific activities performed by CRAs include clinical site monitoring, site initiation, routine monitoring, maintenance of study files, study close out, and retrieval of study materials, as well as on-site and remote monitoring activities including source document verification.

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The challenge faced across all these processes is the volume of data and the different methodologies used worldwide. With around 20,000 CRAs globally, the Centre sought to develop a way to standardise and measure CRA effectiveness quickly via some key performance metrics.

The scalable solution designed by DXC allows data consolidation from multiple disparate sources, including primary data capture solutions, clinical trial management platforms and site management systems to measure CRA effectiveness globally.

Key performance indicators (KPIs) provide evidence based, directional insight on progress, enabling operational processes to be optimised, resources to be prioritised, and accountability to be assigned, to ultimately achieve the organisation's objectives and goals.

Intelligent KPIs, powered by artificial intelligence (AI) and equipped with embedded governance, make the insights and metrics more intelligent, predictive and adaptive.

## Revolutionised clinical trial management

Having worked on systems used within the clinical trial process for many years, the Centre chose to partner with DXC Technology based on its experience and understanding of the process and its leading-edge technology expertise.

Over the past decade, DXC has mastered the AI lifecycle across three specific areas: design, engineering, and scaling, and perfected its expertise in the clinical trial process using AI enabled intelligent solutions to monitor CRA effectiveness, helping to identify, on an individual basis, potential compliance issues and helping CRAs determine the next best actions.

To accelerate the Centre's Al adoption journey, DXC's Analytics team conducted human-centred design thinking workshops to understand the problem and identify potential solutions. Its mission to transform the process stemmed from DXC's understanding of how untenable it was for the Centre to continue tracking data from tens of thousands of CRAs on multiple spreadsheets.

While the effectiveness of a CRA can be determined by factors such as education, experience, personality and motivation, specific metrics can be used to evaluate performance and skills more formally. Metrics incorporated for measurement in the solution included:

- Quality of the investigator initiation package (IIP)
- Initial and verbal informed consent completed
- · Monitoring visit frequency
- IIP due diligence compliance
- · Serious adverse event reporting
- Patient re-consent
- Issue identification and resolution time
- · Sites delinquent in data entry



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Around 40 of the Centre's offices now use the solution to better understand the performance of its 20,000 CRAs worldwide. It supports the Centre in transforming and optimising its clinical trial process by streamlining and accelerating startup time, and automating the effectiveness of CRAs.

DXC's scalable solution allows data consolidation from multiple disparate sources, including primary data capture solutions, clinical trial management platforms and site management systems to measure CRA effectiveness globally.

An evaluation accelerator was built to drive adoption, enabling the Centre to run Al on its own data. This ensures it's safe because it's geared towards acting on internal data, with the evaluation logic helping to evaluate systematically, taking an empirical approach and eliminating guesswork.

Business intelligence and operations performance reports were provided related to: investigator initiation package quality, monitoring visit frequency, due diligence compliance and serious adverse event reporting.

# Harnessing analytics to optimise outcomes

DXC's analytics solution featuring intelligent KPIs powered by AI has helped the Centre solve its operational and technological challenges by capturing and synthesising edge-to-core data from multiple sources, and

converting it into analytical insights to enable data-driven decision-making.

Around 40 of the Centre's offices now use the solution to better understand the performance of its 20,000 CRAs worldwide. It supports the Centre in transforming and optimising its clinical trial process by streamlining and accelerating startup time, and automating the effectiveness of CRAs. It also facilitates faster innovation by quickly uncovering insights, patterns, predictions and recommendations at scale. Better data visibility ensures processes are transparent, auditable, and compliant with regulatory requirements.

With a better understanding of the highest-performing CRAs and specific behaviours and business practices that generate success, the Centre can incorporate these learnings into formal workflows to improve processes. The engine can also educate CRAs to work smarter, with actionable insights used in training and development to identify and address knowledge or protocol compliance gaps for improved performance.

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