

Case Study

R&D

The logo for Red Nucleus, featuring the words "red nucleus" in a white, lowercase, sans-serif font inside a dark red circle. The background of the top half of the page is a stylized, 3D-rendered image of a red, textured, organic structure resembling a cell or a protein, set against a grey and white background with faint, larger-scale organic forms.

red nucleus

PHARMACOVIGILANCE OPERATIONS CASE PROCESSING OPTIMIZATION ASSESSMENT

Client Challenge

The client, a mid-size pharmaceutical company, is expected to quadruple their drug pipeline within the next 2 years. In preparation of its expanding pipeline, the client determined it was necessary to ensure their processes would effectively support the expected increase in cases as a result of their rapid company growth. The client requested an assessment of its Pharmacovigilance (PV) Case Processing business process and systems to identify gaps and potentially leverage new automation technologies available in the industry.

Red Nucleus Solution

The Red Nucleus (RN) Team focused on developing a thorough understanding of the current process as the basis for further analysis. Through a review of existing documentation and a series of interviews with key team members in the US and EU, the RN Team worked collaboratively with the client to create an end-to-end As-Is Process and System Landscape.

In parallel, the RN Team identified and catalogued key challenges and opportunities for improvement. The As-Is assessment highlighted that the client's Case Processing team relied on manual processes and workarounds to compensate for their PV database limitations, including but not limited to manual tracking of critical Case Processing activities and working in siloed operations to complete tasks. These challenges limited overall effectiveness, efficiency, and optimal resourcing.

Based on the analyses of information collected and existing industry knowledge, the RN Team developed an Optimization Roadmap. The roadmap supplied the client with various recommendations and solutions to mitigate the challenges identified in the assessment. The solutions were categorized based on a risk versus benefit analysis and prioritized an implementation timeline to provide a wholistic approach that supported the client's growing portfolio.

Value

As a result of the RN Team's assessment and deliverables, the client Leadership team was positioned to make informed strategic decisions on next steps.

The Process Map and System Landscape highlighted the full scope of low-value, manual, or redundant aspects of the process and current system limitations, respectively. Based on this information, the RN Team developed the Optimization Roadmap with targeted solutions that addressed the specific root cause of issues faced by the Case Processing and Leadership teams. Solutions were classed in categories including automation opportunities, addressing redundant and inefficient processes, and improving system functionality. They spanned from quick short-term wins to medium and long-term strategy. The Optimization Roadmap ensured the client was well-positioned to begin improving their day-to-day processes and begin planning to meet the needs of their expanding organization.

A large, dark red circular graphic containing white text for contact information.

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