Paper AD02

Developing a Shiny Web Application to Address Suboptimal Treatment of Urology Patients Through Predictive Modelling and Improved Communication of Science

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ABSTRACT

Around 20% of men over the age of 55 experience urinary symptoms due to an enlargement of the prostate (LUTS/BPE) and are at risk of disease progression. Most of these men are sub-optimally treated, contrary to published guidelines. More effective communication of scientific information is needed to support physicians' data-driven decisions and improve patient management.
To contribute to this field, we analysed large GSK trial datasets and developed state-of-the-art statistical models that incorporate patient and treatment characteristics to predict symptoms and outcomes. We then developed an educational web application in Shiny that presents the study information in a more digestible manner. This application uses the models to facilitate visualisation and understanding of predicted outcomes for individual profiles. We have translated it into several languages and made it available to physicians worldwide at www.bphtool.com.
Our team faced several challenges while developing the tool, such as the novelty of the approach, software as a medical device regulation, cultural inertia, and overlap of the Shiny developer role with other roles in the company. We believe these challenges are common across the industry.
By sharing our learnings, we hope to help others implement similar approaches effectively for the benefit of the medical community and ultimately the patients.

INTRODUCTION

The emergence of interactive apps and visualisations has significantly transformed the work of data scientists. Their close collaboration with domain experts positions them ideally to create effective prototypes and applications to complement their analyses. However, integrating these new technologies into highly regulated healthcare work environments poses several challenges.

This paper presents an anecdotal example from GSK, where a multidisciplinary team comprising a data scientist, a statistician, and medical affairs and external experts in the urology field conducted a data-reuse modelling study and successfully transformed it into an educational interactive web application at www.bphtool.com. This tool helps medical professionals worldwide understand how risk factors for disease progression interact and affect response to different treatments, reinforcing the importance of an individualised approach for LUTS/BPE management.

This innovative project encountered several challenges. These are the same challenges we anticipate data scientists will face in other similar-sized organisations striving to enhance their data science journey. In this paper, we explore these challenges and propose an effective working approach that enabled the GSK team to overcome these hurdles, leading to the successful development and publication of the study and corresponding web application, i.e., www.bphtool.com.

PROBLEMS FACED

Despite a careful initial plan and high motivation, our limited experience in transforming analyses into external web applications led to unexpected difficulties. As a result, we had to repeatedly reassess our original timeline.

Below, we outline the most significant challenges we encountered, which encompass both internal and external ones.

Problem 1

At GSK and many other pharmaceutical corporations, applications are developed by a central technical department. As a user of new technology from a different background, the Shiny developer (data scientist) may lack the required awareness of the company's digital governance framework for the deployment of web applications, which is necessary to comply with regulations. On the other hand, the department responsible for creating applications may not be aware of the existence of the Shiny framework. This misalignment in ways of working and lack of awareness presents challenges, despite the partial overlap between the roles of a Shiny developer and a regular application developer.
Consequently, the infrastructure for hosting externally facing Shiny applications was not in place.

While the central technical department could create these web applications using established practices, the process would be slower and more complex. Furthermore, we believe that creating an application that supports a data analysis effort should involve the people who perform the data analysis and the intended audience.

Problem 2

Another hurdle is the impact of organisational inertia on business model innovation, which aims to enhance value delivery to specific stakeholder groups while benefiting the company. Resistance to change within corporations can arise from a sense of comfort with existing technologies and processes, as well as the significant organisational changes required for the implementation of new ones.[1] This unavoidable resistance makes it difficult to streamline and adapt the compliance and governance framework for technological and analytical aspects in the pharmaceutical industry.

While this resistance is partly justified by the presence of strict regulations and high cost of failure, it also poses a significant obstacle to taking calculated risks that can help pharmaceutical companies adapt to a changing environment and ultimately benefit patients.

Problem 3

The evolving landscape of regulations surrounding Software as a Medical Device in different geographic regions posed another challenge, as GSK did not traditionally develop software. As a result, internal guidance around these regulations was unclear. Specifically, there was uncertainty about whether our web application would be classified as a medical device in certain countries.

Problem 4

An external challenge is the tendency of clinicians to favour data presented in a format they are accustomed to, prioritising clarity and simplicity over information density, and their unfamiliarity with statistical jargon and advanced concepts. These are secondary observation in studies examining clinicians' perspectives on the emerging data[2,3]. However, we have anecdotally found them to be true in the urology clinical field where we developed our project.
Therefore, new tools need to have an intuitive design for clinicians to facilitate understanding of the complex science that sits behind them.

Internal preference for older types of data visualisation, controlling for the higher immediate cost of developing innovative state-of-the-art solutions, could also be partially motivated by the inability to guarantee long-term maintenance of interactive tools, since they require companies to upkeep their hosting systems and modify the applications as new regulations are instated.

SOLUTIONS IMPLEMENTED

Before we consider how each problem was tackled, we cannot overstate the importance of identifying key figures in each department to help foresee challenges, remove blockers, facilitate smooth communication, and guide a team through unfamiliar internal regulations.

To address the first internal problem, we worked closely with our technical department. Building the necessary infrastructure required extensive meetings with several technical stakeholders while we evaluated different options, trying to balance implementation time and other business considerations such as cost, overlap with other systems, internal governance, and availability of human resources who are more familiar with traditional programming languages. Although we were aware of cloud solutions for external hosting, the long vetting process for external vendors would have been incompatible with our project's timeline. We therefore opted for in-house servers.
Identifying a process to develop a compliant web application was a more complicated effort. In addition to conducting thorough tests to ensure the robustness of the software, it was essential for it to pass a comprehensive security risk analysis. Other related tasks, such as purchasing an external domain and creating firewall exceptions, were taken care of by separate teams. We will not delve into these as different companies are likely to have different internal processes.

To address the second internal problem, organisational inertia, we would like to stress the importance of the advocacy of senior stakeholders to ensure prompt collaboration between departments. Of course, the project needs to be considered valuable enough to justify its cost.

To address the lack of clarity surrounding the regulation of Software as a Medical Device, collaboration was necessary between our Legal, Compliance, and Regulatory departments. Eventually, they created an ad hoc internal panel for assessment and developed new internal guidance, which gave us a clearer path forward. While our software does not meet the criteria of a medical device, we acknowledged the importance of defining its intended use more precisely and accurately. This clarification needed to be reflected throughout the web application by using disclaimers and pop-ups and effectively communicated by all GSK personnel involved in promoting the web app and disseminating study results.

Lastly, to address the external problem, we began by gathering requirements from end users. We also followed existing guidelines on how to present clinical prediction models in clinical settings. We created quick mock-ups and prototypes to validate ideas early on. Stakeholder reviews were held periodically to keep everyone aligned. We also were careful that the tool meets the accessibility standards and can be used on different devices in different languages.

We believe that as new applications emerge to enhance scientific discourse, it is impossible to foresee all the problems that may arise. This is even more likely for companies trying to embark on this new journey, as their company-specific policies might not yet be able to govern the novelty. We believe that the ways of working we employed are ultimately behind the achievement of our goals. Otherwise, the project would have stalled due to our inability to navigate unknown territory.

Our ways of working include the following steps:
1. Identify target audience, outcome, etc.: This helped us clarify our goals.

2. Sketch an interface with the project owner and present a quick proof of concept to a sample of users: This allowed us to visualise our ideas and test their feasibility early in the process.
3. Meet a design expert (if you have one): This ensured that our interface was not only functional but also user-friendly and accessible.
4. Identify a few key people within each department that can help you foresee challenges, help with communication, remove blockers, and point to existing guidance: This enabled us to leverage the expertise and insights of individuals across the company, enhancing our problem-solving capabilities.
5. Contact Legal, Regulatory, and Compliance teams as early as possible: This ensured that our web application complied with all relevant laws and regulations for its Software as a Medical Device classification, mitigating legal risks.
6. Collaborate with the Technical department: This facilitated the technical implementation of our project, ensuring that our web application complied with existing internal protocols for risk mitigation and hosting.
7. Implement features: This was the stage at which our ideas became tangible.
8. Constant feedback and periodic reviews with end users: This ensured that our project remained aligned with user needs and expectations, enabling us to continually improve our product.

Should another team decide to follow these steps, we suggest that they focus on the logic and evaluate them from their company perspective, as they should be modified or collapsed based on organisational structure.

OUTCOME

Despite the lack of a pre-existing procedure to follow, we pioneered the company's first external Shiny application. We also published a successful tool to break the monotony of presenting scientific papers in the same way. Ultimately, we created a useful tool that helps urologists better understand our publications and the impact of specific treatments on various patient outcomes for individual patient profiles. The tool has been translated into three languages, and we are currently tracking adoption metrics such as usage data to quantify its impact. After one year, the tool has been accessed by approximately twenty-five thousand unique healthcare professionals worldwide, and user feedback indicates that it provides valuable information to ultimately inform treatment decisions. Our success opened the door for new partnerships, expanded use of Shiny, and investment in data science capabilities.

GOVERNING IDEA

By following the aforementioned ways of working, our team was able to manage unforeseen pushbacks and build our product incrementally, despite the absence of a pre-existing internal process. This flexible approach allowed for the creation of an innovative web application to complement an analysis, deliver faster output, and invest in new technologies.

CONCLUSION

Despite the challenges faced, which we believe are present in other pharmaceutical corporations, the successful implementation of the project was achieved through a combination of perseverance, innovation, and collaboration. Being aware of some of these challenges, other companies can use our proposed ways of working to navigate an unexplored environment.

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