Exploring the US market landscape and developing strategy for a digital health technology

What our client needed

Our client was looking to explore the routes to reimbursement in the US for their product in early stages of development. The product consisted of an already Food and Drug Administration (FDA) approved class I medical device and a new cloud-based mobile app.

The client was looking to understand the conventional route to reimbursement for the combined product, as well as other applicable reimbursement and patient access schemes (PASs), including the evidence requirements and formal mechanisms for application and review. In addition, the client was interested in the relevant stakeholders and decision-making drivers, as well as the feasibility of the commercial strategies in the context of the US landscape.

How we supported them

We conducted internal stakeholder interviews to understand their perceptions of unmet need experienced by patients and the possible challenges and opportunities the product may face when coming to market.

Using our existing knowledge of reimbursement routes for digital health technologies in the US and wider markets (including both the formal Centers for Medicare and Medicaid Services [CMS] route and additional reimbursement and PAS schemes), we presented our client with a summary of the relevant stakeholder bodies for launching their product. This report included decision-making drivers and potential barriers to access in the US.

Using desktop research, we identified appropriate analogues to the client's product. We investigated the key evidence used to achieve authorisation, the challenges the manufacturers faced and the relevance of these learnings to the client's product.

The outcome

We presented the client with a PowerPoint report detailing the market access and early evidence development opportunities available to them. The report included detailed information of the current reimbursement landscape in the US and the specific reimbursement routes the client's product was likely to be eligible for.

We provided strategic recommendations regarding the optimal routes to reimbursement for our client and the strategies they should follow in order to effectively launch their product into the US market.

The client was able to use the report internally to develop their US market strategy. Using the data presented, the client was able to tactically collect the appropriate evidence, as well as adapt their product design to increase the likelihood of reimbursement status in the US.

How we added value

We used a combination of primary and secondary research to ensure the final deliverable provided detailed and effective strategic recommendations to support the client's market access strategy. In addition to this, we highlighted the current knowledge gaps in our research, that could be investigated further by conducting supplementary primary research with key stakeholders.

We used a collaborative approach to incorporate the client's feedback and needs into the report. The final deliverable included a concise executive summary that combined all workstreams and recommendations to support the client in launching their product into the US market.