ADELPHI VALUES | PROVE Expertise in Access and Value Evidence Outcomes

# Identifying unmet needs in a crowded therapy area to support regulatory approval

## Conducting an extensive literature review of the burden of illness and unmet medical needs in an autoimmune disease for a European regulatory submission

### The challenge

Our client developed an innovative product to treat patients with an autoimmune condition. Despite a wide range of treatment options being available, the target disease continued to be associated with a major global burden on patients, healthcare systems and society.

Our client wanted to identify the unmet needs for patients with the disease to support a regulatory submission for their novel treatment in this crowded therapy area.

### The solution

We provided an integrated solution utilising the significant regulatory expertise of both our PROVE and Patient-Centered Outcomes (PCO) practices.

This included an extensive literature review covering multiple areas of unmet need including:

> Clinical burden

> Humanistic burden

> Economic burden

> Treatment pathways

We focused on understanding and highlighting the unmet needs in the target therapy area using a multi-perspective approach.

### Key results

We provided a comprehensive report to support the overall product value story, which clearly highlighted the unmet needs in the relevant patient population for patients and healthcare systems, and which made the case for the need for a new therapeutic option for patients.

The report also identified potential opportunities for the product within the current treatment pathway, according to the agreed label indication.

### Value to the client

The results were incorporated into the European regulatory submission as part of the key evidence to pave the way for regulatory success for our client's product. In turn, this helped to improve the lives of patients by providing a novel and effective treatment option.

**"The team took on board what we wanted to achieve and tried hard to achieve the task, offering good insights along the way"**