

nisms underlying AID. Instead, non-genetic biomarkers are vital to detect changes in the biological processes associated with patients' individual diseases.

Moreover, AID is a potential side effect of cancer immunotherapies when the immune system becomes overstimulated.³ Through weaponizing the body's immune system against cancer, immunotherapies are already showing great promise, although only a small percentage of patients currently respond to treatment.^{4,5} Therefore, monitoring the effectiveness of immunotherapies and preventing irAEs such as AID requires a CDx tool that can help restore the delicate balance between immune stimulation and repression⁶ (Figure 1).

We need new CDx solutions to inform AID treatment, as well as to potentially restore

the balance of the immune system in those suffering from cancer and being treated with immunotherapies. In both cases, autoantibodies could be the answer.

Autoantibodies as biomarkers in cancer immunotherapies and AID

Autoantibody production underlies both cancer immunotherapies and AID, and is highly detectable in patients' blood serum. Therefore, although so far overlooked for systematic analysis, a CDx tool that can accurately monitor autoantibody signatures could enable precision medicine in cancer immunotherapies and AID.

Autoantibody profiling could help to stratify patients into clinically relevant disease subgroups, allowing targeted cancer treatments, as well as helping to monitor the risk of irAEs in patients undergoing immunotherapy. In turn, this could help save time and resources during drug development, while also improving treatment success rates and patient outcomes.

To showcase the value of this approach, we are currently conducting research collaborations with the US National Cancer Insti-

tute (NCI) and the German National Center for Tumor Diseases (NCT). The aim is to identify novel autoantibody signatures associated with specific cancer disease states and outcomes using Protagen's proprietary biomarker development engine, SeroTag.

What's next for precision medicine?

Applying a precision medicine approach in AID and immuno-oncology could transform drug development processes and treatment outcomes, potentially relieving significant financial strain on the healthcare industry and improving millions of lives. However, appropriate biomarker CDx tools have not yet been adopted in these markets, and as such could hinder the progression of promising new cancer immunotherapies and AID treatments.

Therefore, we must identify other biomarkers beyond those rooted in genetics to harness the full advantages of precision medicine. Together with other genomic, proteomic and metabolomic biomarkers in a 'multiplex-multimodality' approach, autoantibody profiles could be a promising avenue towards unleashing the true potential of precision medicine to combat cancer and AID. ■

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