

## **Navigating Adverse Immunostimulation: A Practical Guide For Clinical Researchers**

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As drug development advances toward increasingly complex investigational medicinal products (IMPs), early clinical trials face growing challenges from unwanted or unexpected activation of the immune system, commonly referred to as adverse immunostimulation (AIS). Despite its clinical relevance, AIS remains difficult to diagnose and manage due to variability in presentation and a lack of standardized protocols.

At the Centre for Human Drug Research (CHDR), we have implemented systematic approaches to evaluate AIS through standardized biomarker sampling and tailored management strategies. These methods not only mitigate risks during early-phase trials but also provide valuable insights into the IMP's mechanism of action, ultimately enabling more efficient and informative drug development. This publication offers a practical framework for clinical researchers by outlining our recommendations for AIS evaluation, management, and sampling procedures.

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