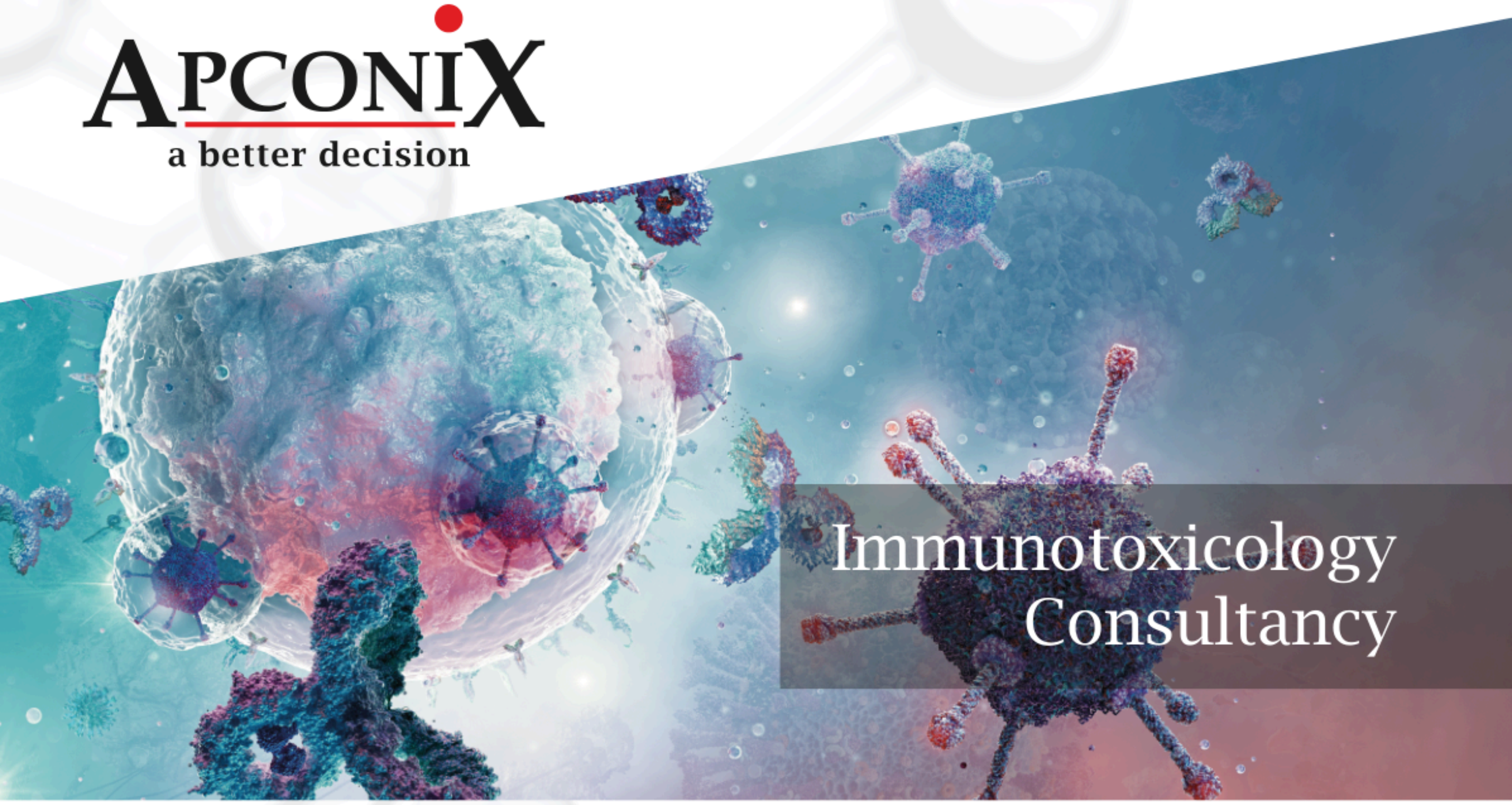
APCONIX

a better decision



Immunotoxicology Consultancy

Assessing the Role of the Immune System in Drug Safety

ApconiX has the expertise, knowledge and understanding to support you to develop bespoke, cost effective IND/CTA enabling programmes. We will guide you every step of the way, ensuring you are informed and supported as your project progresses.

Our Experienced Immunotoxicologists Will:

- Guide the strategic design and placement of nonclinical experimentation
- Investigate the mechanistic basis and translational consequence of immunological signals
- Advise you to make informed, scientifically driven project/pipeline decisions and navigate the development of regulatory strategies
- Interpret immunological data

THE KING'S AWARDS FOR ENTERPRISE 2025 INNOVATION

THE KING'S AWARDS FOR ENTERPRISE 2024 INTERNATIONAL TRADE

THE QUEEN'S AWARDS FOR ENTERPRISE: INTERNATIONAL TRADE 2022

The immunological effects of drugs range from intended effects to off target and unanticipated liabilities

Drug Discovery Risk Assessment

Manipulating the immune system to achieve a desired therapeutic effect potentially comes with significant risks. One of the most important aspects of drug safety is how these risks can be understood and managed. A variety of assessments can guide and inform projects, including scientific reviews, target safety and weight of evidence assessments.

Derisking Approaches in Strategic Pipeline Design

Some complex safety related issues span a portfolio of drugs and can affect multiple projects in a company's development pipeline. Developing a strategy to be systematically applied across a pipeline can help provide a contextualised decision making approach for moving the best candidates forward.

Design and Interpretation of In Vitro and In Vivo Pharmacodynamic and Safety Studies

Delivering a scientifically driven, fit for purpose and regulatory compliant nonclinical package for pharmacology and toxicology is key for project progression. Careful selection and design of studies is critical to ensure the validity of project data from proof of concept through to clinical trial design to avoid costly mistakes and ensure timely completion.

"I have found the team to be very responsive to requests and I feel that they are part of the team delivering to our project."

VP of Biology,
UK Biotech Company

Nonclinical and Clinical Biomarker Selection

Being able to monitor parameters of efficacy and/or potential toxicity and translate this information from nonclinical to clinical studies is critical. Selecting the right biomarkers is important for the translational value of preclinical studies and can have a major role in a drugs risk benefit profile.

Toxicity Signal/Concern Interpretation and Investigation

The immune system is complex, and immune mediated toxicities occur in toxicology programs and in the clinic. Through careful investigation and expert insight, it is possible to understand the mechanisms involved, the translational relevance, and to take the appropriate course of action to drive projects forward.

CRO Selection and Auditing

Delivering relevant studies that are undertaken competently and efficiently is vital. Using our vast experience of the CRO landscape, we will impartially help you find the right partners to conduct pivotal pharmacology and toxicological studies. The correct oversight can ensure a project generates robust data, at the right time, and within budget, making the development process as efficient and effective as possible.

"Your immunological knowledge is really key in helping us understand both the likely mechanisms in play and the limits of what can be quantified / predicted."

Head of Toxicology,
Large Pharmaceutical Company

Partnering with you to mitigate and manage immunotoxicity risks at all stages of drug development

Meet Some of Our Team

Dr Sean Hammond

Sean is the Immunotoxicology Lead at ApconiX, and is involved in the identification and mitigation of immune safety issues at all stages of drug development. He has discovery, project and investigative toxicology experience across multiple drug modalities including small molecules, biologicals and advanced/novel therapies, and is an expert in delivering project and drug pipeline strategies. His areas of specialty are IO agents, novel/challenging modalities, immunogenicity and hypersensitivity reactions. He is also as an Honorary Senior Lecturer at the University of Liverpool where he conceptualises and supervises immunotoxicology research.

Dr Lolke Dehaan

Lolke has over 20 years experience in large molecule toxicology as a discovery and project toxicologist, holding various leadership roles including immune-oncology safety lead at Medimmune/AstraZeneca and VP toxicology at ADC therapeutics. Lolke has extensive experience with IO and ADC agents and has supported the development of numerous agents, including durvalumab (Imfinzi®), and loncastuximab tesirine (Zynlonta®). Lolke supports client strategies for toxicology as well as in wider biologics drug development in the respiratory & inflammation, cardiovascular and oncology therapeutics areas.

Marie Cumberbatch

Marie has over 35 years of experience gained in large pharma and academia. She specialises in the development and validation of oncology, immuno-oncology and immunotoxicology biomarkers for small and large molecules in the context of mechanism, resistance, patient selection and safety from early target identification through to clinical trials. Marie supports clients in the immuno-oncology space with nonclinical model selection, biomarker analyses, design of in vitro mechanistic studies, and has deep expertise in interrogating clinical tissue based and circulating biomarker outputs.

Stephen Kirk

Stephen has 30 years of experience in nonclinical drug development, Stephen offers design, oversight, and interpretation of nonclinical safety studies as well as a solid understanding of GLP's and nonclinical CRO's. He provides support for regulatory documentation including CTD Module 2, pre-IND, CTA, IB, ODD and PIP/PSP authoring, as well as identifying gaps in nonclinical safety packages and providing regulatory strategy advice.

Dr Emma Bishop

Emma Bishop is a Senior Scientist within the immunotoxicology team at ApconiX. She holds a PhD from the University of Birmingham which focused on the metabolic and functional roles of TNF-a signalling in T cells in health and autoimmune disease. Emma primarily works within the safety science group, where her strong immunology background is applied to deliver high quality target safety assessments as a primary author and more widely through building risk identification and interpretation capabilities. Emma also has practical experience with in vitro assay development and interpretation, including for mechanistic toxicology application within an industrial setting.

Dr Amy Shepherd

Amy is an experienced immunologist with 10 years' experience in safety programme design and has previously led cross functional drug development teams globally within a large CRO. Amy supports the Immunotoxicology Team as a Senior Project Manager, supporting projects from discovery and lead compound selection through to first in human clinical studies. Amy has a wealth of experience with different modalities and provides a key insight into the CRO landscape. She has a strong reputation for building collaborative client relationships and managing projects.

Dr Stephen Lynch

Stephen is a Senior Scientist at ApconiX. He holds a PhD in pharmacology which focused on mechanistic toxicology evaluation in complex in vitro models. Stephen has industrial experience with in vitro models and stem cells, which he gained in tenures at Medicine Discovery Catapult and Biograd. At ApconiX, Stephen is involved in the authoring of immune and GI focused target safety assessments. Stephen values mechanistic toxicology and being actively involved in impactful, client-driven research.

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