

## Acuity Target Safety Assessments (TSAs)

### Knowledge is Power

Acuity TSAs are created by project toxicologists, supported by artificial intelligence, to provide an understanding of target and modality safety liabilities and a risk mitigation plan.

### Our Concise and Customised Acuity TSAs Will:

- Increase your knowledge of potential safety liabilities
- Support timely and informed decision making
- Maximise the use of your limited resources

**acuity**

Expert-driven - AI-enabled

**“The target safety evaluation was perfect. Our toxicologist was very happy with the final document as was the project team. Not only was the document great, it was delivered on time and the turn-around time for the edits was outstanding.”**

James Murray, Toxicologist,

Sanofi.

# At least 50% of drug safety failures are attributable to target related effects



## Understand Potential Liabilities Early and Facilitate Informed Decision Making

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### What Is a Target Safety Assessment?

A TSA brings together public domain information (target homology, gene and protein expression profiles, transgenic and mutation phenotype data) with the expertise of experienced toxicologists into a concise report that identifies key risks by organ/tissue.

### Why Are TSAs Important in Drug Discovery and Development?

Understanding potential safety liabilities associated with a target at an early point in a project helps you to anticipate and manage issues before they arise. An Acuity TSA forms the basis of a risk mitigation plan including the ranking of risks and potential next steps.

### What Can Be Included in an Acuity TSA?\*

- Executive summary
- Homology, expression, transgenic and mutation phenotypes
- Key risks identified and categorised by tissue
- Competitor information (public domain)
- Mitigation plans with ranking of risks and potential next steps
- Embedded PowerPoint ready for presentation

\*Depending on client needs

**Acuity TSAs are authored by project toxicologists familiar with the project team environment and objectives**

## **Meet Some of the Team**

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### **Professor Ruth Roberts**

A co-founder of ApconiX, Professor Ruth Roberts has over 25 years of experience in leading roles in drug safety within large pharma. Ruth is also chair and Director of Drug Discovery at the University of Birmingham, UK and previously Global Head of Regulatory Safety at AstraZeneca. With over 140 publications in peer-reviewed journals, she is former president of the BTS, EUROTOX and the Academy of Toxicological Sciences as well as former secretary of SOT. Ruth has received numerous awards including the SOT Achievement award, the EUROTOX Bo Holmstedt award and the SOT Founders award for outstanding leadership in toxicology.



### **Dr James Sidaway**

Dr James Sidaway is an experienced and innovative toxicologist having worked for over 20 years in the pharmaceutical industry with AstraZeneca and as an independent consultant. As a molecular investigative toxicologist he helped resolve safety issues for a wide range of drug discovery and development projects across the major therapy areas. He has also developed advanced in vitro models for organ toxicity screening, pioneered the application of novel technology and informatics platforms and has a strong track record of delivering target safety assessments.



### **Dr Claire Sadler**

Dr Claire Sadler is an experienced project toxicologist and former Director of Discovery Safety within AstraZeneca. Claire specialises in early project safety assessment, identifying and mitigating risks from target identification through to early clinical trials. She has worked across multiple therapy areas including immunology, cardiovascular, oncology and infection as well as many drug platforms including small molecules, proteins and novel therapies. Claire has been directly involved in bringing many candidate drugs to clinical trials submitted through different regulatory agencies.

**“Working with ApconiX was effortless! They have provided high quality target safety assessments with a focus on comprehensive interpretation of findings. The information provided has helped contribute to decisions on activities when moving early molecules forward.”**

## Meet Some More of the Team

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### **Dr Duncan Armstrong**

Dr Duncan Armstrong is an expert pharmacologist with an international reputation in secondary and safety pharmacology gained over 18 years in drug discovery and development at AstraZeneca and Novartis. Having worked with project teams at all stages of discovery and development across multiple therapy areas, he has a track record of optimising small molecule off-target safety profiles and in understanding and interpreting target-related safety risks. Duncan enjoys bringing his passion for pharmacology to successful collaborative teams.



### **Dr Nicholas Coltman**

Dr Nicolas Coltman recently completed his PhD in in vitro pre-clinical toxicological research (hepatotoxicity, genotoxicity and advanced in vitro models) through a BBSRC iCASE Scholarship with Sygnature Discovery Ltd at the University of Birmingham. Before this, Nic gained a master's degree in molecular mechanistic toxicology and a post graduate certificate in advanced research methods and skills. He then gained invaluable industry experience first at Envigo and then at Sygnature Discovery. A creative and skilled scientific professional, Nic brings innovative new thinking to the team alongside a solid knowledge of molecular and mechanistic toxicology.



### **Dr Sean Hammon**

Dr Sean Hammon holds a PhD in immunopharmacology from the University of Liverpool focused on developing experimental and conceptual means to address T-cell mediated hypersensitivity reactions. He has long-standing links with drug safety research at Liverpool where he received the Syngenta prize for pharmacology at degree level and where he maintains an academic profile. He has several publications focused on the immunotoxicological aspects of small molecular weight compounds and immunecheckpoint inhibitors. Sean particularly values working with interdisciplinary experts to drive rational, data-led decision making in drug development projects.



### **Dr Helen Garside**

Dr Helen Garside has over 10 years of experience in the pharmaceutical industry focused on predictive and mechanistic toxicology. She has expertise in early project toxicology gained through roles in discovery safety and safety pharmacology, supporting projects across multiple therapy areas. Helen has a passion for collaborative working and applying the latest technology to toxicology.



Contact the ApconiX team for more details

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