

## **Knowledge is Power**

Acuity Target Safety Assessments are created by project toxicologists, supported by Artificial Intelligence, to provide an understanding of target safety liabilities and a risk mitigation plan.

## **Our Concise and Customised Target Safety Assessments Will:**

- Be individually tailored to the needs of each project
- Support timely and informed decision making
- Boost confidence with a comprehensive search using the latest AI technology
- Include an optional annual update



"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."

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







## Understand Potential Liabilities Early and Facilitate Informed Decision Making

#### **What Is a Target Safety Asssessment?**

A target safety assessment 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 Target Safety Assessments Important in Drug Discovery and Development?

Understanding potential safety liabilities associated with a target, early in projects helps you to anticipate and manage issues before they arise. An Acuity Target Safety Assessment forms the basis of a risk mitigation plan including the ranking of risks and potential next steps.

### What Can Be Included in an Acuity Target Safety Assessment?\*

- 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 Target Safety Assessments are authored by project toxicologists familiar with the project team environment and objectives.

#### **Meet Some of the Team**



#### **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 was the recipient of numerous awards including the SOT Achievement award, the EUROTOX Bo Holmstedt award and the SOT Founders award for outstanding leadership in toxicology.



#### 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 oncology, infection, immunology and cardiovascular, and on many drug platforms including small molecules, proteins and novel therapies. Claire has been directly involved in bringing many candidate drugs to clinical trial, submitted through different regulatory agencies.



#### **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.

"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**



#### **Dr Russell Huby**

Dr Russell Huby is an experienced toxicologist with expertise in oncology, discovery project toxicology and investigative mechanistic toxicology. He has extensive experience in early stage projects gained from over 20 years in the pharmaceutical industry and has conducted numerous target safety assessments across multiple therapy areas. Russell is a pragmatic problem solver with an eye for the possible and the practicable.



#### **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 Andrew Winkley**

Dr Andrew Winkley has over 20 years of drug safety experience in industry at GSK, AstraZeneca and Vertex. He has a broad scientific background that includes mechanistic and regulatory toxicology, and biochemistry. His experience covers the complete life cycle of drug development from discovery to late-stage development in several therapeutic areas including orphan indications, neuroscience, pain therapeutics, inflammatory diseases, infectious diseases and oncology. Andrew has been involved in bringing several candidate molecules to clinical trials and most recently completed an NDA/MAA for a cystic fibrosis drug. Andrew is a highly adaptive project toxicologist who can assimilate and interpret a broad range of data from various disciplines to provide clear guidance to the project team.