Dr Jörg Täubel
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Patient safety is pivotal in phase I trials

Clinical trials sit at the heart of therapeutic development and new medicines, ensuring they are conducted safely remains paramount.

Robust design of phase I clinical trials is critical to ensure patient safety during the process of developing new therapies and drugs.

This is particularly important when potential new treatments move into first-in-human studies in phase I before conducting more detailed phase II and phase III patient studies.

Dr Jörg Täubel, Scientific Lead at the Richmond Research Institute, says robust trial protocols are crucial at this stage to ensure patient safety.

Risk management

Ensuring that all relevant non-clinical data from animal models and in-vitro testing are available supports risk management in phase I clinical trials and enables participating patients to be fully informed of those risks.

Dr Täubel says: "It is very important to fully understand the mode of drug action and the safety aspects before first-in-human trials. Armed with this knowledge first in human trials can be conducted within the target patient population which will maximise the data yield."

Robust risk management strategies need to be in place to ensure patient trials are as well managed as trials in healthy volunteers where we already have very sophisticated processes. Data yield must be maximised, with the optimum numbers of patients enrolled. Careful consideration of the data collected, particularly in adaptive protocols, may mean fewer research participants are needed for the study.

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Improving trial design

The Richmond Research Institute is dedicated to understanding and improving the safety of pharmaceuticals, with a particular focus on cardiac health, diabetes, liver disease and more recently COVID-19 research.

Dr Täubel says better stratifying groups of patients who are testing medications is an area of specialty, and represents progress on the path of personalised medicines.

The institute also has an interest in improving trial design to include population groups that may not normally participate in studies to make such trials more relevant and inclusive to different groups, he adds. We are committed to studying under-researched areas to help make medicines safer for diverse patient populations.

Written by **Mark Nicholls**

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