CliniSafe®

Guidance to Concomitant Medication Management.

Enhance Human Subject Protection, Optimize Data Quality

CLINISAFE®

CLINISAFE®

Protecting **Your** *Clinical* **Trials**

RELIABILITY AND QUALITY YOU CAN TRUST

CliniSafe is a web-based concomitant medication management system developed specifically to improve the way in which clinical trials are conducted. A unified centralized approach can significantly reduce variability and standardizes outcomes, thereby reducing risk.

Establishing concomitant medication drug rule compliance is a well-recognized problem for the clinical trial industry and errors occur at a vast cost.

Moreover, there is growing emphasis from the industry regulators to demonstrate safety and maintain the delivery of good clinical practice.

CliniSafe is a ground-breaking advance on current manual medication review processes, providing a real-time supportive interface, specialist service and customer care team.

Many users interact with the clinical study protocol. CliniSafe enables sponsors to have greater control by providing uniform management across the study team.

The New version of CliniSafe presents on an Integrated Research Platform and provides a customizable dashboard based on your study role. So program managers can view and perform high-level project tasks, while specialists can have easy access to drug dictionary technology applying sophisticated design to complex study protocols to a level that has previously been unachievable. The system is presented though a single interactive interface allowing users to get the information they need all in one place.

Configurable *Solution*

FLEXIBILITY TO MEET YOUR NEEDS

The benefits of computers to assist with drug prescribing in healthcare has been well established for over a decade and has been shown to both reduce and eliminate error. It would now be almost unimaginable for many doctors to work in an environment without such support as it has become part of their daily lives. However, addressing the challenges in concomitant medication management within clinical trials has proved a greater “nut to crack” and has only recently become possible due to the development of both a configurable approach and advancing technologies. Clinisafe is the first generation of such technologies and was invented, developed and programed in house with over a decade of understanding on the reliable delivery of a simple end user solution to the problem. Like search engines there is more going on than meets the eye. Most importantly it is remarkable easy to use, replacing not creating a task. A simpler way of doing what is already being done but easier, faster, more accurately and without stress.

CliniSafe is built with patented technology to providing a flexible and configurable electronic medication management solution.
Sophisticated high-level IT architecture within CliniSafe allows individual protocol design, providing a fully integratable and configurable solution with the reliability you can depend on to fulfil the specific demands and exacting requirements of multi-centre global clinical trials.

A key CliniSafe feature is the precision by which we enforce study protocol drug rules combined with a seamless instant user feedback. Centrally standardized, “live” concomitant medication management offers substantial improvement in terms of safety and quality over current paper-based systems.

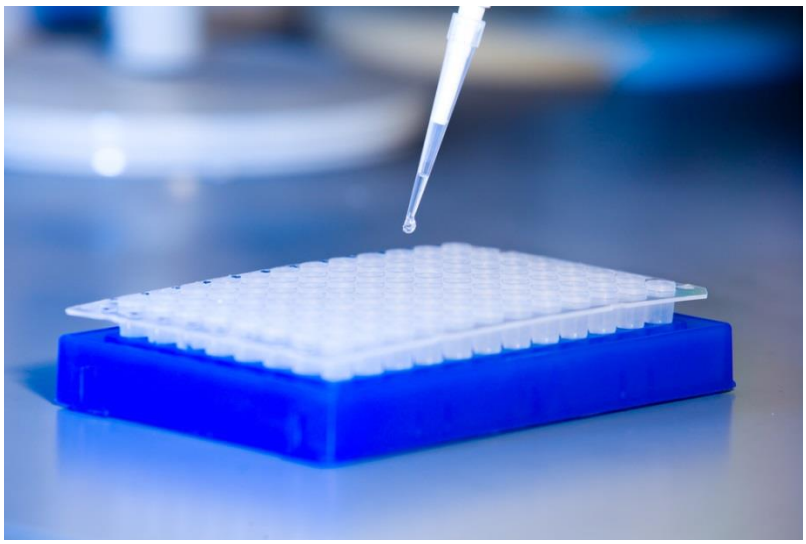
Challenges *and Experience*

PRECISION

CliniSafe personnel have first-hand experience in over 200 trials facing the issues and challenges in reviewing a clinical trial protocol to ensure the successful and safe enrolment of a subject.

Patient medication management will not remain a paper-based process for very much longer. Relying on the unsupported skills and knowledge of individual clinicians and their ability to accurately access published formularies is slowly becoming a “thing of the past”.

CliniSafe simplifies this complex information transfer process enabling the sponsor to precisely stipulate the drug rules at any given point in time.
By improving existing communication systems & processes it is a major advance on current paper-based methodologies.



CLINISAFE®

Critical *and Complex*

CHANGING LANDSCAPE OF CLINICAL TRIALS

Monitoring and managing concomitant medications within clinical trials has become an increasingly critical and complex task.

Complexity comes from many directions, not least that there are now over 7,000 officially licensed generic drugs, along with the added difficulties posed by trade names, non-unique names and multi- ingredient preparations.

Incorporating pre-clinical safety information (e.g. CYP 450) into a protocol has added another level of complexity, which is often external to the expertise of the investigator, monitors and site staff.

Therefore, the ability to consistently and accurately match patients to the protocol has become an ever increasing challenge for organizations running clinical trials. CliniSafe provides an elegant, efficient and user friendly approach to concomitant medications management.

REDUCE ERROR/SAVE TIME

"CliniSafe allows me very easily to manage complex protocol drug rules. Having immediate access to an electronic medication management system saves me and my staff a considerable amount of time and improves our decision making. Most of all I sleep easy at night because I know the answer is right."

Professor Chris McWilliam, UK

CLINISAFE®

The **Benefits**

RELIABILITY & CONSISTENCY

SAFETY

The paramount concern in the conduct of clinical trials is patient safety. With an increasing requirement to actually demonstrate safety, CliniSafe provides an electronic medium to deliver live accurate information to investigator sites. This allows safety with regards to the drug-checking aspects of clinical trials to be vastly increased.

DATA

Data wastage in monetary terms due to protocol violations associated with concomitant medications management can reach staggering proportions. CliniSafe significantly improves data quality by consistently lowering error, thus reducing intra-site and inter-site variability. Reducing error helps optimize robust endpoints and minimize data wastage and ultimately reduces the risk of study failure.

COST

By simplifying project management CliniSafe enhances resource efficiency in medication management across disciplines including nurses, investigators, monitors and pharmacovigilance teams. Importantly, from an operational perspective, the CliniSafe solution greatly enhances pre-screening methodology for investigators and site staff searching for new and eligible patients. Reducing prospective drug development program timelines realizes tangible benefits.

PROTOCOL MANAGEMENT

CliniSafe facilitates complex protocol design allowing the time, cost and effort of pre-clinical work to be effectively translated into later clinical studies.

ADAPTIVE

CliniSafe maintains global uniformity of standards in this complex arena, using a centralized web-based service throughout the trial. The solution enables rapid deployment of any protocol changes which become immediately available to all sites.

CLINISAFE®

Putting **Patient** *Safety* **First**

CLINISAFE - "THE SCIENCE OF SAFETY"

If the world is to become a safer place to take medicines, all pharmacists will need to have an understanding of the human and technological factors underpinning safe systems of work – the 'science of safety'.

Within clinical trials understanding human error and maintaining a systems thinking approach to safety culture is essential. Methodology is required that not only supports colleagues in the event of an error, but also considers the role of patients and carers.

Pharmacists already have an excellent understanding of the practical aspects of safe system design, and indeed this is supported by recent industry comments in IT support for the sector:

IT Support for Clinical Trials Medicines Management

"Inadvertent protocol violation in clinical trials due to concomitant use of medicines contraindicated by the protocol can affect around 5% of clinical trial patients per year. As such, this issue has a significant impact, not only on the cost and efficacy of clinical research, but also on the quality of patient care. It is an issue that all health professionals should be concerned about and is of particular relevance to pharmacists, given their routine contact with patients concerning medicine supply and administration."

"Modern prescribing and medicines management decision support technology, supported by high quality medicines data, has the potential to address the inadvertent concomitant prescribing issue by enabling comprehensive and consistent screening for contraindicated medicines in patients on clinical trials. This is an area that should be explored both by healthcare professionals and by health IT systems suppliers."

Stephen Goundrey-Smith
Healthcare IT Pharmacist
Royal Pharmaceutical Society of Great Britain.

CLINISAFE®

CliniSafe *Features*

GLOBAL SOLUTION

US FDA CFR 21 PART 11
Digital Signatures
Audit Trail
Documented Design

GLOBAL
Multi-lingual
Multi-National
Culturally Specific
Time Stamp
Unicode

APPLICATION
ASP.Net
SQL Server
GAMP 5 validated

INFRASTRUCTURE
Reliable and Resilient
Secure
Encrypted
Scalable
Data Protection

FUNCTIONALITY
Mutually Exclusive
Complimentary

AWARDS

SCRIP - Best Technological Development in Clinical Trials

Queen's Award for Enterprise

Institute of Director's Award for Innovation

Corporate Headquarters
Kaman Court, Faraday Way, Blackpool, UK
E-mail: info@clinisafe.com
Tel: +44 (0) 7702 403077
www.clinisafe.com