

# CliniSafe®

Centralized Pharmacy Reading For Clinical Trials

Demonstrate Patient Safety, Optimize Data Quality



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CLINISAFE®  
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## CENTRALIZED EQUALS STANDARDIZED

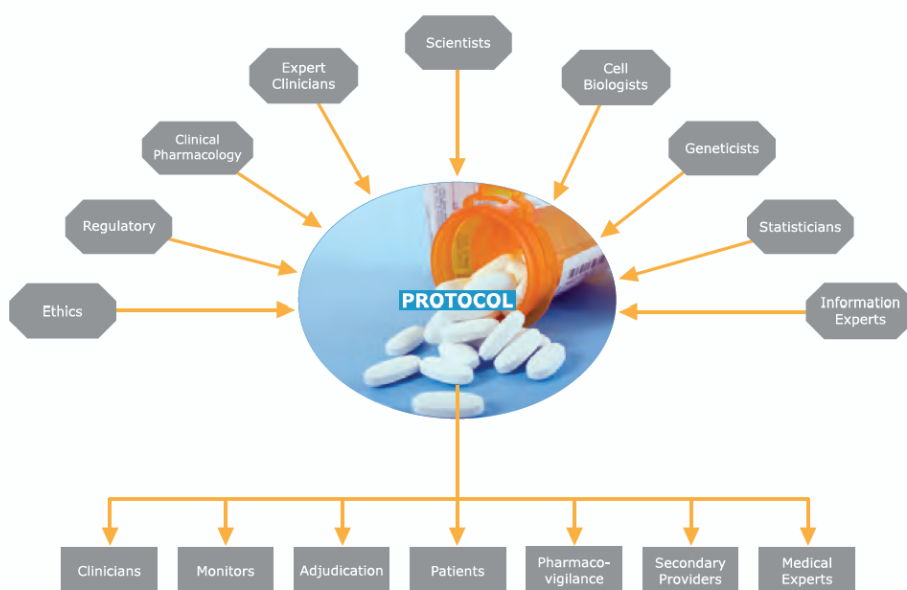
*CliniSafe is a web-based concomitant medication management system developed specifically for use within global clinical trials. Centralized management of protocol drug rules significantly reduces variability and standardizes outcomes, thereby reducing risk.*

Establishing concomitant medication protocol drug rule compliance is a well recognized problem for the clinical trial industry. 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 manual medication review, providing a real-time interactive solution, 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 of study protocol concomitant medication drug rules.



# Protecting Your Clinical Trials

## RELIABILITY AND QUALITY YOU CAN TRUST

*CliniSafe provides a simple real-time online service to centrally check the relevance of protocol individual or multiple concomitant drugs or drug combinations.*

- ▶ Maximize Patient Safety
- ▶ Minimize Risk
- ▶ Increase Probability Of Trial Success With Robust Data Quality
- ▶ Enhance Recruitment
- ▶ Support Your Investigator Network
- ▶ Simplify Management Of Complex Protocols
- ▶ Reduce Monitoring Time
- ▶ Significant Financial Value



*Poor quality data from just one patient is sufficient to fail a clinical trial*

### CASE STUDY:

**Study:** Spasticity in multiple sclerosis

- ▶ 18 subjects altered their concomitant medication at some stage within the study period

**Results:** Failed on primary endpoint

- ▶ One treatment group subject identified as an outlier
- ▶ Received beta-interferon prior to baseline - prohibited
- ▶ Data approached significance including the outlier: ( $p=0.051$ ; 95% CI: -1.029, -0.004 points)
- ▶ Excluding an outlier from the placebo group resulted in a significant difference between-groups ( $p=0.013$ , 95% CI: -1.118, -0.131 points)
- ▶ Repeat study 2009, outcome positive.

Collin, C., Davies, P., Mutiboko, I. K., Ratcliffe S. (2007) European Journal of Neurology, 14: 290 -296.



# Configurable Solution

## FLEXIBILITY TO MEET YOUR NEEDS

*The benefits of electronic medication management in healthcare systems are well established in both reducing and often eliminating error. However, inaccuracy in concomitant medication management within clinical trials remains a major cause of protocol violation, as such systems are not configurable to manage individual protocol drug rules.*

CliniSafe is built with multi-axial technology providing a flexible and configurable electronic medication management solution.

Sophisticated high-level IT architecture within CliniSafe guarantees individual

protocol mapping, 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 the service enforces study protocol drug rules combined with seamless instant user feedback. Centrally standardized, “live” concomitant medication management offers substantial improvement in terms of safety and quality over both the current paper-based and EDC methodologies.



# Challenges and Experience

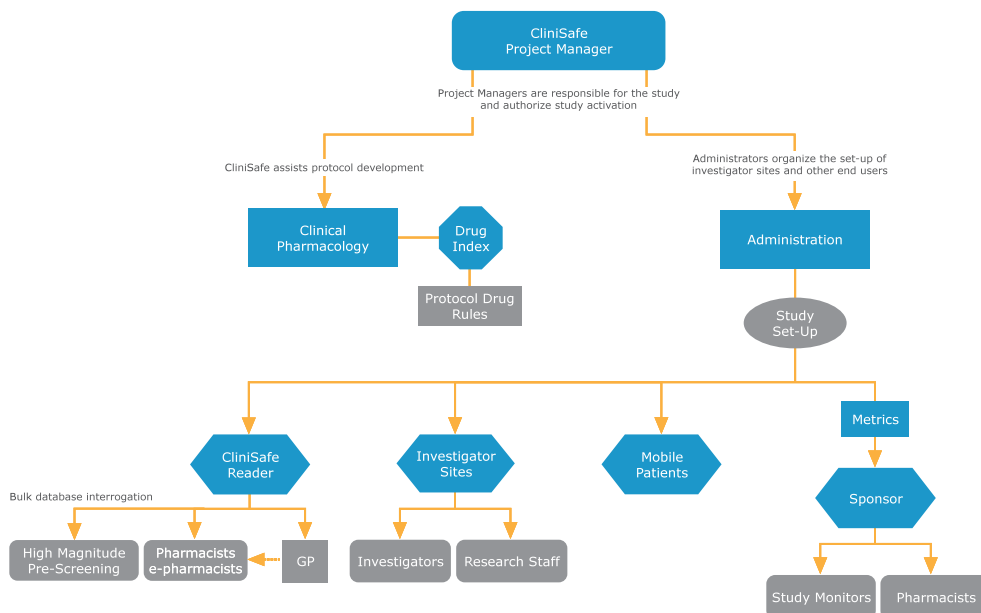
## PRECISION

*CliniSafe personnel have first-hand experience of the issues and challenges that face investigators when reviewing a clinical trial protocol to ensure the successful and safe enrolment of a patient.*

Until recently, patient medication management has remained a paper-based process relying on the skills and knowledge of individual clinicians and their ability to accurately access

published formularies.

CliniSafe simplifies this process enabling research pharmacists to precisely stipulate the drug rules at any given point in time. Providing a vehicle by which information can directly support investigators to apply the latest protocol requirements and any amendments is a major advance on current paper-based methodologies.



# Critical *and* Complex

## CHANGING LANDSCAPE OF CLINICAL TRIALS

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*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 brand names and compound drugs.

Incorporating pre-clinical safety information (e.g. CYP 450) into protocol drug rules has added another level of

complexity which is often external to the expertise of investigators, monitors and site staff.

Therefore, the ability to consistently and accurately match patients to the protocol has become an increasing challenge for organizations running clinical trials.

CliniSafe provides an elegant, efficient and user friendly approach to concomitant medications management, allowing support from consultancy services and expert pharmacists.



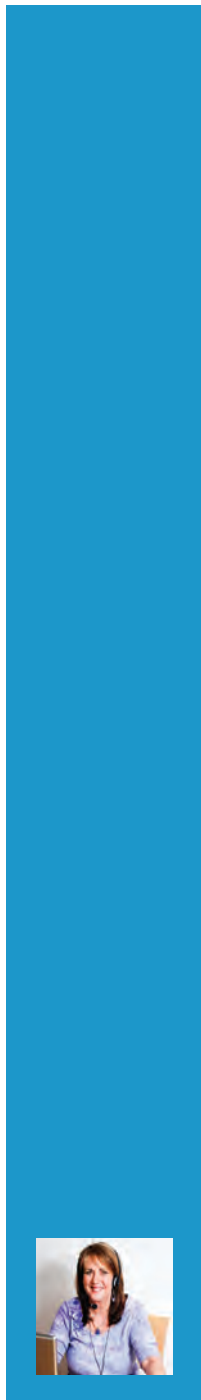
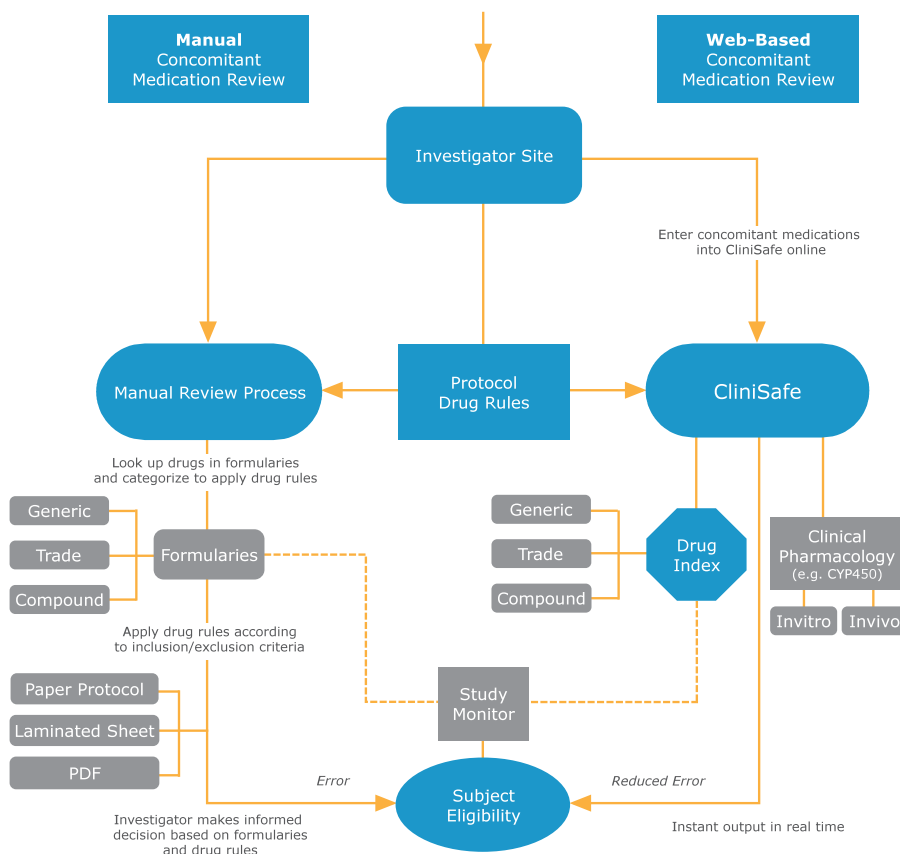
# Using CliniSafe



## 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."*

*Professor Chris McWilliam, UK*



# 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

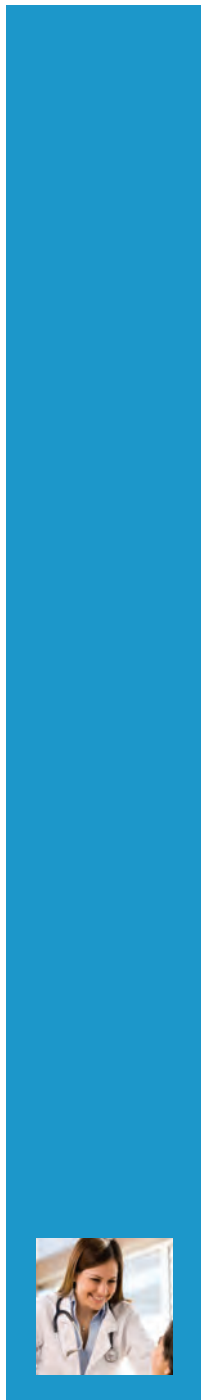
across disciplines including nurses, investigators, monitors and pharmacovigilance teams. Importantly, from an operational perspective, the CliniSafe solution greatly enhances pre-screening methodology for investigators and site staff searching for new and eligible patients. Reducing prospective drug 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.



# 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 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  
UK Data Protection Act

### FUNCTIONALITY

Mutually Exclusive  
Complimentary



**CliniSafe: The Key Benefits**

- ✓ **IMPROVE DATA QUALITY**
- ✓ **REDUCE DATA WASTAGE**
- ✓ **ROBUST STUDY FINDINGS**
- ✓ **REDUCE DEVELOPMENT TIME**
- ✓ **SIGNIFICANT FINANCIAL VALUE**
- ✓ **MINIMAL INVESTMENT**
- ✓ **SUPPORT PRE-SCREENING ACTIVITY**
- ✓ **IMPROVE RECRUITMENT**
- ✓ **GLOBAL STANDARDIZATION**
- ✓ **ENHANCE PROTOCOL DESIGN**
- ✓ **INCREASE PATIENT SAFETY**



**Corporate Headquarters**

*Kaman Court, Faraday Way, Blackpool, UK*

*E-mail: [info@clinisafe.com](mailto:info@clinisafe.com)*

*Tel: +44 (0) 7540 723 524*

*[www.clinisafe.com](http://www.clinisafe.com)*