PROJECT MANAGEMENT

# INSIGHT

SCOPE

INSIGHT

InSIGHT, our clinical trial management system (CTMS), is a web-based, powerful, and integrated information solution that consolidates and visualises operational and clinical data from multiple sources to generate a complete overview of study information. It allows you to turn existent data into real knowledge, supporting faster and better decision-making throughout the life of a trial.

As the clinical research world changes, the pressure on businesses to lead the way in innovation and technical excellence is greater than ever. An increasing amount of data from multiple sources requires management and analysis. With our **passion for innovation** and our **in-depth technological expertise**, we turn the latest developments into **tailor-made clinical research solutions**.

SCOPE's clinical trial management system (CTMS) InSIGHT is your tool to **maintain oversight through every project stage**. Visibility of all project processes allows for optimization of clinical study management like never before.

InSIGHT supports project planning by setting up project-specific expectations. It is a Global Tracking Platform providing an **overview and real-time insights for study status information** both in the form of trackers and status dashboards.

InSIGHT contains a document management system that supports the complete document lifecycle from document draft to released electronically signed document. Our CTMS can be used as a **location-independent collaboration platform** for the complete project team. With SCOPE, you gain the integration, visibility, control and agility you need to run an exceptional and efficient clinical research development program.

# INSIGHT – THE FACTS

### PROJECT PLANNING

Set your project-specific expectations for essential documents, subject recruitment, monitoring visit (report) timelines and many more

### PROJECT TRACKING & VISUALIZATION

— From action items to insurances, protocol deviations, regulatory submissions, subject recruitment, site status and many other areas – InSIGHT keeps track of data points from A-Z

— Our Essential Documents Tracking and Monitoring Visit Report Documents Tracking is based on project specific document plans. Automated tracking occurs based on InSIGHT document workflows

— The Performance Dashboards allows to for an adjustable overview at the desired information level: study, country, site

— Built-in task management provides a transparent and efficient way of getting things done

— Alerts can be flexibly set and used to stay informed on how the documentation progresses

— Provides an overview of the involved study teams, countries and sites

### DATA IMPORT

Subject Data Import can be enabled regardless of which (e)CRF you use

— Makes manual subject entry into InSIGHT obsolete

— Feeds into all required documents, trackers and dashboard

— Eliminates discrepancies between different data sources

### CONFIGURATION & CUSTOMIZATION

— Role based access permissions for stakeholders of the specific project only provide access on an 'as needed basis' and protection of confidential information

— Study Project Management grants users access to the study and / or individual Investigational Trial Sites based on operational needs

— Real-time access allows data analysis in accordance to the user's areas of responsibility

## DOCUMENT MANAGEMENT

InSIGHT's powerful Document Management supports your complete document lifecycle: from document template to draft document to approval and electronic signature to filing of the final document

— The Document Template Manager allows for study specific adaptation of document templates

— InSIGHT automatically populates documents with system data

— Flexible Document Workflows can be assigned to individual system users or user groups

— Co-Authoring speeds up document finalization

— PDF converter supports conversion to and combination of documents as PDF

— E-Signature feature allows to electronically sign a document and verify existing signatures

— Document Filing Tool displays in your libraries which documents are already filed in your (e)TMF

**Further time-savers**

— Batch Document Processing saves time

— Integration with MS Office Package lets you work with known applications

## COLLABORATION TOOLS

— InSIGHT's collaboration tools facilitate and speed up shared efforts of your team

— Shared Document Repository allows sharing of documents within SCOPE and with Sponsors

— Workflows & Task Notifications notify team members to relevant tasks

— Alerts / Reminders support planning of the daily working life

— Announcements keep the project team up to date with the latest project developments

— Custom MS Outlook-Add-in facilitates document sharing with non-InSIGHT users

## ELECTRONIC SIGNATURE

— Timely document signature loop completion and document authorization

— A verification tool can be optionally employed to ensure that the document content did not change since signature loop was started

**INSIGHT**

## GLOBAL CONTACT DATABASE

— SCOPE's internal contact database, that is accessible to SCOPE staff has only, grown organically over the years and still continues to grow daily

— Facilitates identification of suitable investigational sites for your trial in a timely manner

— Dedicated processes ensure that contact data updates requiring follow-up action are notified to affected projects

## CUSTOMIZATION & TECHNICAL SUPPORT

— Having the development team in-house allows us to swiftly and flexibly react to your additional project specific needs

— In-house user support is available for timely and straightforward issue resolution

## QUALITY & REGULATORY

— InSIGHT is developed and validated per state-of-the-art approaches and globally accepted industry development standards, e.g. GAMP5

— InSIGHT is validated throughout its system lifecycle to ensure that regulatory requirements such as ICH E6 and 21 CFR part 11 are met

### COMPETENCE

InSIGHT's development is based on operational excellence and fits SCOPE´s processes like a glove.

### TRUST

Confidence & data integrity with controlled access to our integrated KaleidoSCOPE platform.

### CUSTOMER-CENTERED

Tailored to the specific needs of clients and users: Our custom CTMS provides great flexibility to integrate 3rd party systems driving a "best fit" solution.

### OVERSIGHT

Leave out the guess and get a complete overview in real-time with our sophisticated dashboards & trackers.

### EFFICIENCY

InSIGHT´s powerful document management supports collaboration from draft document to approval to e-signature and release to final filed document.

INSIGHT

STRATEGIC
DEVELOPMENT

MEDICAL
WRITING

BIOSTATISTICS AND
SAS® PROGRAMMING

QUALITY
MANAGEMENT

CLINICAL
OPERATIONS

CLINICAL DATA
MANAGEMENT

SAFETY
MANAGEMENT

REGULATORY
AFFAIRS

SCOPE International AG
Konrad-Zuse-Ring 18
68163 Mannheim, Germany
Phone +49 621 42939 0

For further information
please contact SCOPE's
Business Development Team:
contact@scope-international.com
www.scope-international.com

CONTACT